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 June 30, 2021
or

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

For the transition period from to

Commission File Number 001-38787

CYCLERION THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Massachusetts	**83-1895370**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
245 First Street, 18th Floor, Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	(Zip Code)

(857) 327-8778
Registrant's Telephone Number, Including Area Code

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

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☒

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

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

As of July 27, 2021, the registrant had 43,276,749 shares of common stock, no par value, outstanding.

CYCLERION PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2021
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties. All statements in this report, other than statements of historical facts, including statements about future events, financing plans, financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations, are forward-looking statements that involve certain risks and uncertainties. Use of the words “may,” “might,” “will,” “would,” “could,” “should,” “believes,” “estimates,” “projects,” “potential,” “expects,” “plans,” “seeks,” “intends,” “evaluates,” “pursues,” “anticipates,” “continues,” “designs,” “impacts,” “affects,” “forecasts,” “target,” “outlook,” “initiative,” “objective,” “designed,” “priorities,” “goal” or the negative of those words or other similar expressions may identify forward-looking statements that represent our current judgment about possible future events, but the absence of these words does not necessarily mean that a statement is not forward-looking.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, our actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national, or global political, economic, business, competitive, market and regulatory conditions and the following:

- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching and commercializing our product candidates, including CY6463;
- the coronavirus (“COVID-19”) pandemic affecting our clinical trials and other operating activities;
- our relationships with third parties, collaborators and our employees;
- our ability to execute our strategic priorities;
- our ability to finance our operations and business initiatives;
- the success of collaboration or license arrangements of our product candidates;
- whether the praliciguat out-license will result in the creation of any therapies for the treatment of patients with kidney disease;
- the uncertain utility, development, promise, and commercialization of praliciguat;
- whether any development, regulatory, and commercialization milestones or royalty payments provided for in the agreement with Akebia (as defined below) will be achieved;
- the impact on our business of workforce and expense reduction initiatives;
- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
- the safety profile and related adverse events of our product candidates;
- the efficacy and perceived therapeutic benefits of our product candidates, their potential indications and their market potential;
- U.S. and non-U.S. regulatory requirements for our product candidates, including any post-approval development and regulatory requirements, and the ability of our product candidates to meet such requirements;

- our ability to attract and retain employees needed to execute our business plans and strategies and our ability to manage the impact of any loss of key employees;
- our ability to obtain and maintain intellectual property protection for our product candidates and the strength thereof;
- our future financial performance, revenues, expense levels, payments, cash flows, profitability, tax obligations, capital raising and liquidity sources, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- the impact of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- potential indemnification liabilities we may owe to Ironwood after the Separation (as defined below); and
- trends and challenges in the markets for our potential products.

See the “Risk Factors” section in Item 1A of our annual report on Form 10-K for the fiscal year ended December 31, 2020, and elsewhere in this Quarterly Report on Form 10-Q for a further description of these and other factors. We caution you that the risks, uncertainties, and other factors referenced above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot assure you that we will realize the results, benefits, or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. There can be no assurance that (i) we have correctly measured or identified all of the factors affecting our business or the extent of these factors’ likely impact, (ii) the available information with respect to these factors on which such analysis is based is complete or accurate, (iii) such analysis is correct or (iv) our strategy, which is based in part on this analysis, will be successful. All forward-looking statements in this report apply only as of the date of this report or as of the date they were made and, except as required by applicable law, we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise.

Cyclerion Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)
(Unaudited)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,390	$ 54,395
Related party accounts receivable	—	127
Prepaid expenses	766	816
Other current assets	1,833	3,163
Total current assets	72,989	58,501
Restricted cash, net of current portion	—	3,837
Property and equipment, net	153	6,865
Operating lease right-of-use asset	—	43,402
Other assets	2,590	2,773
Total assets	$ 75,732	$ 115,378
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,386	$ 1,149
Related party accounts payable	—	286
Accrued research and development costs	2,240	1,421
Accrued expenses and other current liabilities	3,375	7,294
Short-term note payable	3,509	3,509
Current portion of operating lease liabilities	—	3,293
Total current liabilities	10,510	16,952
Operating lease liabilities, net of current portion	—	38,933
Commitments and contingencies	—	—
Stockholders' equity		
Common stock, no par value, 400,000,000 shares authorized and 43,275,249 issued and outstanding at June 30, 2021 and 400,000,000 shares authorized and 34,047,300 issued and outstanding at December 31, 2020	—	—
Accumulated deficit	(193,010)	(163,429)
Paid-in capital	258,258	222,949
Accumulated other comprehensive loss	(26)	(27)
Total stockholders' equity	65,222	59,493
Total liabilities and stockholders' equity	$ 75,732	$ 115,378

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Revenue from license agreement	$ 3,000	$ —	$ 3,000	$ —
Revenue from development agreement	—	—	62	—
Revenue from related party	—	749	$ —	$ 1,763
Total revenues	3,000	749	3,062	1,763
Cost and expenses:				
Research and development	12,054	13,794	20,146	30,619
General and administrative	6,241	6,627	11,606	13,518
(Gain) / loss on lease modification and termination	881	—	881	(2,113)
Total cost and expenses	19,176	20,421	32,633	42,024
Loss from operations	(16,176)	(19,672)	(29,571)	(40,261)
Interest and other income, net	(6)	138	(10)	499
Net loss	$ (16,182)	$ (19,534)	$ (29,581)	$ (39,762)
Net loss per share:				
Basic and diluted net loss per share	$ (0.45)	$ (0.70)	$ (0.85)	$ (1.43)
Weighted average shares used in calculating:				
Basic and diluted net loss per share	35,707	27,791	34,899	27,730
Other comprehensive loss:				
Net loss	$ (16,182)	$ (19,534)	$ (29,581)	$ (39,762)
Other comprehensive loss:				
Foreign currency translation adjustment (loss) gain	1	(12)	1	(10)
Comprehensive loss	$ (16,181)	$ (19,546)	$ (29,580)	$ (39,772)

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

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

	Common Stock		Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity (deficit)
	Shares	Amount				
Balance at December 31, 2019	27,598,133	$ —	$ 183,376	$ (85,627)	$ (20)	$ 97,729
Net loss	—	—	—	(20,228)	—	$ (20,228)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	156,761	—	1		—	$ 1
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	4,036		—	$ 4,036
Foreign currency translation adjustment					2	$ 2
Balance at March 31, 2020	27,754,894	—	187,413	(105,855)	(18)	81,540
Net loss	—	—	—	(19,534)	—	(19,534)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	102,816	—	155	—	—	155
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	3,952	—	—	3,952
Foreign currency translation adjustment	—	—	—	—	(12)	(12)
Balance at June 30, 2020	27,857,710	$ —	$ 191,520	$ (125,389)	$ (30)	$ 66,101

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

	Common Stock		Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity (deficit)
	Shares	Amount				
Balance at December 31, 2020	34,047,300	$ —	$ 222,949	$ (163,429)	$ (27)	$ 59,493
Net loss	—	—	—	(13,399)	—	(13,399)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	82,625	—	27	—	—	27
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,921	—	—	1,921
Share-based compensation expense related to issuance of stock options to non-employees	—	—	391	—	—	391
Foreign currency translation adjustment	—	—	—	—	—	—
Balance at March 31, 2021	34,129,925	—	225,288	(176,828)	(27)	48,433
Net loss	—	—	—	(16,182)	—	(16,182)
Issuance of common stock - June 2021 equity private placement and ATM	9,087,547	—	30,497	—	—	30,497
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	57,777	—	133	—	—	133
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,942	—	—	1,942
Share-based compensation expense related to issuance of stock options and RSUs to non-employees	—	—	398	—	—	398
Foreign currency translation adjustment	—	—	—	—	1	1
Balance at June 30, 2021	43,275,249	$ —	$ 258,258	$ (193,010)	$ (26)	$ 65,222

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

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

	Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,581)	$ (39,762)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	376	1,239
Net loss on disposal of property and equipment	6,322	194
(Gain) / loss on lease modification and termination	881	(2,113)
Share-based compensation expense	4,652	7,989
Changes in operating assets and liabilities:		
Related party accounts receivable	127	723
Prepaid expenses	50	(294)
Other current assets	(121)	38
Operating lease assets	1,344	(4,555)
Other assets	183	(851)
Accounts payable	237	(246)
Related party accounts payable	(286)	294
Accrued research and development costs	819	(549)
Operating lease liabilities	(1,048)	(1,342)
Accrued expenses and other current liabilities	(3,919)	(4,166)
Net cash (used in) operating activities	(19,964)	(43,401)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	—	(1,480)
Proceeds from sale of property and equipment	1,464	59
Net cash provided by (used in) investing activities	1,464	(1,421)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from June 2021 equity private placement and ATM	30,497	—
Proceeds from exercises of stock options and ESPP	160	155
Proceeds from short-term note payable	—	3,509
Net cash provided by financing activities	30,657	3,664
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1	(10)
Net increase (decrease) in cash, cash equivalents and restricted cash	12,158	(41,168)
Cash, cash equivalents and restricted cash, beginning of period	58,232	102,621
Cash, cash equivalents and restricted cash, end of period	$ 70,390	$ 61,453
Supplemental cash flow disclosure:		
Cash paid for initial direct costs of lease modification	$ —	$ 6,507
Non-cash investing activities		
Fixed asset purchases in accounts payable and accrued expenses	$ —	$ 9
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 70,390	$ 56,462
Restricted cash	—	4,991
Total cash, cash equivalents and restricted cash	$ 70,390	$ 61,453

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

1. Nature of Business

Nature of Operations

Cyclerion Therapeutics, Inc. ("Cyclerion", the "Company" or "we") is a clinical-stage biopharmaceutical company on a mission to develop treatments that restore cognitive function. Our lead asset, CY6463 (previously known as, IW-6463), is a pioneering, central nervous system ("CNS")-penetrant, soluble guanylate cyclase (sGC) stimulator that is currently in clinical development for Alzheimer's disease with vascular pathology (ADv), and Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS), and cognitive impairment associated with schizophrenia (CIAS). sGC stimulators are small molecules that act synergistically with nitric oxide (NO) as positive allosteric modulators of sGC to boost production of cyclic guanosine monophosphate (cGMP). cGMP is a key second messenger that, when produced by sGC, regulates diverse and critical biological functions in the CNS including neuronal function, neuroinflammation, cellular bioenergetics, and vascular function.

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

Cyclerion Securities Corporation, a wholly owned subsidiary, was incorporated in Massachusetts on November 15, 2019, and was granted securities corporation status in Massachusetts for the 2019 tax year. Cyclerion Securities Corporation has no employees.

Company Overview

The Company's mission is to develop treatments that restore cognitive function. Its priorities are advancing its ongoing CY6463 clinical programs and next generation compound, CY3018.

CNS assets. CY6463 is an orally administered CNS-penetrant sGC stimulator that is being developed as a symptomatic and potentially disease modifying therapy for serious CNS diseases. Nitric oxide sGC-cGMP is a fundamental CNS signaling network, but it has not yet been leveraged for its full therapeutic potential. CY6463 enhances the brain's natural ability to produce cGMP, an important second messenger in the CNS, by stimulating sGC, a key node in the NO-sGC-cGMP pathway. This pathway is critical to basic CNS functions and deficient NO-sGC-cGMP signaling is believed to play an important role in the pathogenesis of neurodegenerative diseases. Agents that stimulate sGC to produce cGMP may compensate for deficient NO signaling.

On January 13, 2020, we announced positive results from our Phase 1 first-in-human study that provided the foundation for continued development of CY6463. The Phase 1 healthy participant study results indicate that CY6463 was well tolerated. Pharmacokinetic (PK) data, obtained from both blood and cerebral spinal fluid (CSF), support once-daily dosing, with or without food, and demonstrated CY6463 penetration of the blood-brain-barrier with CSF concentrations expected to be pharmacologically active.

On October 14, 2020, we announced positive topline results from our CY6463 Phase 1 translational pharmacology study in healthy elderly participants. Treatment with CY6463 for 15-days in this 24-subject study confirmed and extended results seen in the earlier first-in-human Phase 1 study: once daily oral treatment demonstrated blood-brain-barrier penetration with expected CNS exposure and target engagement. Results also showed significant improvements in neurophysiological and objective performance measures as well as in inflammatory biomarkers associated with aging and neurodegenerative diseases. CY6463 was shown to be safe and generally well tolerated. Significant effects on cerebral blood flow and markers of bioenergetics were not observed in this study of healthy elderly participants. We believe that these results, together with nonclinical data, support continued development of CY6463 as a potential new medicine for serious CNS diseases.

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

will be supported in part by a grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program, which provides Cyclerion with $2 million of funding over two years. Startup activities are ongoing for our Phase 1b clinical study in CIAS, with enrollment expected to begin in the second half of 2021.

Our next generation CNS asset, CY3018, is a differentiated CNS-penetrant sGC stimulator with greater CSF-to-plasma exposure relative to CY6463. CY3018 is intended to expand the potential of sGC stimulation for the treatment of disorders of the CNS.

Non-CNS assets. We have other assets that are outside of our current strategic focus. These non-core assets are not being internally developed at this time and with the exception of praliciguat, are available for licensing to a third-party partner. *Praliciguat* is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into a License Agreement with Akebia Therapeutics, Inc. ("Akebia") relating to the exclusive worldwide license to Akebia of our rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing the pharmaceutical compound praliciguat and other related products and forms thereof enumerated in such agreement. *Olinciguat* is an orally administered, once-daily, vascular sGC stimulator that was evaluated in a Phase 2 study of participants with sickle cell disease. We released topline results from this study in October 2020.

The Separation

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

June 2021 Equity Private Placement

On June 3, 2021, the Company entered into a Common Stock Purchase Agreement (the "June 2021 Equity Private Placement") for the private placement of 5,735,988 shares of the Company's common stock, for total gross proceeds of approximately $18 million. The closing of the June 2021 Equity Private Placement occurred on June 7, 2021. The Company did not utilize the services of a placement agent or broker and accordingly incurred no material related transaction fees or commissions.

At-the-Market Offering

On July 24, 2020, the Company filed a Registration Statement on Form S-3 (the "Shelf") with the Securities and Exchange Commission (the "SEC") in relation to the registration of common stock, preferred stock, debt securities, warrants and units of any combination thereof for an aggregate initial offering price not to exceed $150.0 million. The Shelf was declared effective as of July 31, 2020. On September 3, 2020, the Company entered into a Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") with respect to an at-the-market offering (the "ATM Offering") under the Shelf. Under the ATM Offering, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Jefferies as its sales agent. The Company will pay to Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. During the three and six months ended June 30, 2021, the Company sold 3,351,559 shares of its common stock for net proceeds of $12.5 million under the ATM Offering, after deducting commissions paid to Jefferies of approximately $0.4 million.

Basis of Presentation

The condensed consolidated financial statements and the related disclosures are unaudited and have been prepared in accordance with accounting principles generally accepted in the U.S. Additionally, certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission on February 25, 2021.

In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all normal recurring adjustments considered necessary for a fair presentation of the Company's financial position and the results of its operations for the interim periods presented. The results of operations for the three and six months ended June 30, 2021, and 2020 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period.

The condensed consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries, Cyclerion GmbH, and Cyclerion Securities Corporation. All significant intercompany accounts and transactions have been eliminated in the preparation of the accompanying condensed consolidated financial statements.

Going Concern

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

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

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

2. Summary of Significant Accounting Policies

The accounting policies of the Company are set forth in Note 2. *Summary of Significant Accounting Policies* to the consolidated financial statements contained in the Company's 2020 annual report on Form 10-K. The Company includes herein certain updates to those policies.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of expenses during the reported periods. On an ongoing basis, the Company's management evaluates its estimates, judgments, and methodologies. Significant estimates and assumptions in the consolidated financial statements include those related to revenue, impairment of long-lived assets, valuation procedures for right-of-use assets and operating lease liabilities, income taxes, including the valuation allowance for deferred tax assets, research and development expenses, contingencies, share-based compensation and going concern. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the

results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as discussed elsewhere in the notes to the consolidated financial statements, the Company did not adopt any new accounting pronouncements during the six months ended June 30, 2021 that had a material effect on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses. This standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. As a smaller reporting company, ASU 2016-13 will become effective for the Company for fiscal years beginning after December 15, 2022, and early adoption is permitted. The Company is currently evaluating the impact that ASU 2016-13 will have on its financial statements and related disclosures.

In May 2021 the FASB issued Accounting Standards Update No. 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, a consensus of the Emerging Issues Task Force (EITF) , which amends the FASB Accounting Standards Codification (ASC or the "Codification") to provide explicit guidance, and, thus, reduce diversity in practice, on accounting by issuers for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after the modification or exchange. This amendment provides that for an entity that presents earnings per share (EPS) in accordance with Topic 260, the effects of a modification or an exchange of a freestanding equity-classified written call option that is recognized as a dividend should be an adjustment to net income (or net loss) in the basic EPS calculation. The amended guidance becomes mandatorily effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, and should be applied prospectively to modifications or exchanges occurring on or after the effective date. The Company is currently evaluating the impact that ASU 2021-04 will have on its consolidated financial statements and related disclosures.

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

3. Related Party Transactions

Development Agreement with Ironwood

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

Under the Development Agreement, the Company provided certain research and development services to Ironwood at mutually agreed upon rates and the amounts earned are recorded as revenue from related party for the three and six months ended June 30, 2020. Such research and development activities were governed by a joint steering committee composed of representatives of both Ironwood and the Company. Ironwood and the Company have agreed not to renew the Development Agreement beyond the end of its initial term on March 31, 2021. These transactions under the Development Agreement were considered related party transactions due to Mark Currie's role as President of the Company through December 31, 2020, and board member of Ironwood. In January 2021, Mark Currie's role transitioned from President of the Company to a senior advisor on a consulting basis. Therefore, effective January 2021, transactions under the Development Agreement are no longer accounted for as related party transactions. The Company recorded approximately $0.8 million and $1.8 million as related party revenue for the three and six months ended June 30, 2020, respectively.

4. Fair Value of Financial Instruments

The Company's cash equivalents are generally classified within Level 1 of the fair value hierarchy. The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values as of June 30, 2021 and December 31, 2020 (in thousands):

	Fair Value Measurements as of June 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 64,407	$ —	$ —	$ 64,407
Cash equivalents	$ 64,407	$ —	$ —	$ 64,407

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

During the six months ended June 30, 2021, and 2020, there were no transfers between levels. The fair value of the Company's cash equivalents, consisting of money market funds, is based on quoted market prices in active markets with no valuation adjustment.

The Company believes the carrying amounts of its prepaid expenses and other current assets, restricted cash, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of these amounts.

5. Property and Equipment

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

	June 30, 2021	December 31, 2020
Software	$ 2,214	$ 2,214
Computer and office equipment	44	44
Leasehold improvements	—	14,894
Property and equipment, gross	2,258	17,152
Less: accumulated depreciation and amortization	(2,105)	(10,287)
Property and equipment, net	$ 153	$ 6,865

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

Depreciation and amortization expense of the Company's property and equipment was approximately $0.1 million and $0.6 million for the three months ended June 30, 2021 and 2020, respectively, and approximately $0.4 million and $1.2 million for the six months ended June 30, 2021 and 2020, respectively.

During the three and six months ended June 30, 2021, the Company wrote off $6.3 million of leasehold improvements as a result of its Head Lease termination (see Note 8 to the Condensed Consolidated Financial Statements) and recorded a non-cash loss of $6.3 million. The loss on disposal of property and equipment was recognized as a component of operating expenses in the condensed consolidated statements of operations and comprehensive loss for the six months ended June 30, 2021.

6. Accrued Expenses and Other Current Liabilities

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

	June 30, 2021	December 31, 2020
Accrued incentive compensation	$ 724	$ 1,720
Salaries	489	514
Accrued vacation	336	555
Professional fees	965	689
Accrued severance and benefit costs	639	3,640
Other	222	176
Accrued expenses and other current liabilities	$ 3,375	$ 7,294

7. Commitments and Contingencies

Other Funding Commitments

In the normal course of business, the Company enters into contracts with clinical research organizations and other third parties for clinical and preclinical research studies and other services and products for operating purposes. These contracts are generally cancellable, with notice, at the Company's option and do not have any significant cancellation penalties.

Guarantees

On September 6, 2018, Cyclerion was incorporated in Massachusetts and its officers and directors are indemnified for certain events or occurrences while they are serving in such capacity.

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of June 30, 2021 and December 31, 2020.

8. Leases

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

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

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

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

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

On April 30, 2021, the Company entered into a Termination Agreement for its Head Lease as initially amended on February 28, 2020, and further amended on September 15, 2020. Pursuant to the Termination Agreement, the Company surrendered the leased space of approximately 57,000 square feet to the building's landlord. The Company did not pay any termination fees in connection with the Termination Agreement. As a result of the termination of the Head Lease, the related right-of-use asset was written off, the lease liability was derecognized, and the $3.8 million security deposit was returned to the Company and recorded as part of our cash balance. In total, the Company recognized a loss on the termination of the Head Lease of $0.9 million during the three months ended June 30, 2021. The loss is included in "General and administrative" expenses on our condensed consolidated statement of operations and comprehensive loss.

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

Lease cost is recognized on a straight-line basis over the lease term. For the three and six months ended June 30, 2021, the Company recognized a total of approximately $0.6 million and $2.2 million, respectively, of total lease costs. Variable lease costs not subject to an index or rate are recognized as incurred. For the three and six months ended June 30, 2021, the Company recognized a total of approximately $0.2 million and $0.7 million, respectively, of variable lease costs related to the Head Lease, as amended.

For the three and six months ended June 30, 2020, the Company recognized a total of approximately $2.2 million and $4.9 million, respectively, of total lease costs and $0.5 million and $1.5 million, respectively, of variable lease costs, related to the Head Lease, as amended.

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

	Six Months Ended June 30,	
	2021	2020
Decrease in right-of-use assets related to lease modifications and termination	$ 42,058	$ 21,386
Decrease in operating lease liabilities due to lease modifications and termination	$ 41,177	$ 23,499
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$ 1,887	$ 4,249
Weighted-average remaining lease term of operating leases (in years)	—	9.0
Weighted-average discount rate of operating leases	—	9.7%

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

For the six months ended June 30, 2020, gross sublease income of $0.5 million was recorded related to the sublease. Net sublease income of approximately $0.1 million was recorded in interest and other income in the condensed consolidated statements of operations and comprehensive loss for the six months ended June 30, 2020.

On September 15, 2020, concurrent with execution of the Second Lease Amendment, the Company entered into the Sublease Termination Agreement to terminate its sublease of 15,700 rentable square feet. Under the terms of the Sublease Termination Agreement, the subtenant was relieved of its obligation to provide future cash rental payments to the Company. The agreements requiring the former subtenant to provide licensed rooms and services to the Company free of charge through the original sublease term survived the sublease termination. The Company expects to receive the benefit of the licensed rooms and services beginning in the third quarter of 2021. The letter of credit security deposit related to the sublease was released.

The Company determined that the Sublease Termination Agreement constitutes a non-monetary exchange under ASC 845 Nonmonetary Transactions (“ASC 845”) where, in return for the free rooms and the services, the Company agreed to terminate its rights and obligations under the sublease agreement. In accordance with ASC 845, the Company determined that the accounting for the transaction should be based on the fair value of assets or services involved. The Company estimated the fair value of the rooms and services to be approximately $1.5 million and $2.9 million, respectively. Accordingly, prepaid rooms and services of $4.4 million were recorded upon the sublease termination, of which $1.8 million is recorded in other current assets and $2.6 million is recorded in other assets in the condensed consolidated balance sheets as of June 30, 2021. Termination fee income of $3.1 million was recognized related to the rooms and services, after considering the rent receivable balance of $1.3 million outstanding from the subtenant. The remaining unamortized direct costs of $0.2 million were written off.

The Company determined that the licensed rooms represent a lease under ASC 842. Once the Company obtains control of the rooms, the prepaid rooms balance will be reclassified from other assets to a ROU asset, and the related lease expense will be recorded on a straight-line basis over the lease term. The Company determined that the licensed services represent a non-lease component, which will be recognized separately from the lease component for this asset class. The expense related to the licensed services will be recognized on a straight-line

basis over the period the services are received. Both the lease expense and services expense will be recognized as a component of research and development costs in the consolidated statements of operations and comprehensive loss.

9. Share-based Compensation Plans

In 2019, Cyclerion adopted share-based compensation plans. Specifically, Cyclerion adopted the 2019 Employee Stock Purchase Plan ("2019 ESPP") and the 2019 Equity Incentive Plan ("2019 Equity Plan"). Under the 2019 ESPP, eligible employees may use payroll deductions to purchase shares of stock in offerings under the plan, and thereby acquire an interest in the future of the Company. The 2019 Equity Plan provides for stock options and restricted stock units ("RSUs").

Cyclerion also mirrored two of Ironwood's existing plans, the Amended and Restated 2005 Stock Incentive Plan ("2005 Equity Plan") and the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan ("2010 Equity Plan). These mirror plans were adopted to facilitate the exchange of Ironwood equity awards for Cyclerion equity awards upon the Separation as part of the equity conversion. As a result of the Separation and in accordance with the EMA, employees of both companies retained their existing Ironwood vested options and received a pro-rata share of Cyclerion options, regardless of which company employed them post-Separation. For employees that were ultimately employed by Cyclerion, unvested Ironwood options and RSUs were converted to unvested Cyclerion options and RSUs.

The 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, during the year ended December 31, 2019, Cyclerion recognized a one-time incremental expense of approximately $0.3 million for the vested stock options and will recognize an incremental expense of approximately $7.5 million for the unvested stock options over their remaining vesting period.

The following table provides share-based compensation reflected in the Company's condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2021, and 2020 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 935	$ 1,880	$ 1,917	$ 3,801
General and administrative	1,405	2,073	2,735	4,188
	$ 2,340	$ 3,953	$ 4,652	$ 7,989

A summary of stock option activity for the six months ended June 30, 2021, is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Average Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	7,426,356	$ 11.87	7.0	1,178
Granted	510,000	3.20		
Exercised	(41,078)	2.21		
Cancelled or forfeited	(1,174,680)	10.02		
Outstanding as of June 30, 2021	6,720,598	$ 11.59	6.8	$ 2,312
Exercisable at June 30, 2021	4,127,008	$ 13.91	5.7	$ 563

As of June 30, 2021, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested time-based stock options held by the Company's employees is $10.9 million and the weighted average period over which that expense is expected to be recognized is 3.18 years.

A summary of RSU activity for the six months ended June 30, 2021 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2020	294,913	$ 14.52
Vested	(71,854)	15.70
Forfeited	(97,704)	14.41
Unvested as of June 30, 2021	125,355	$ 13.91

As of June 30, 2021, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested restricted stock units by the Company's employees is 1.2 million and the weighted-average period over which that expense is expected to be recognized is 1.5 years.

The Company has granted to certain employees performance-based options to purchase shares of common stock. These options are subject to performance-based milestone vesting. During the three and six months ended June 30, 2021, and 2020 there were no shares that vested as a result of performance milestone achievements. The Company recorded no share-based compensation expense related to these performance-based options for the three and six months ended June 30, 2021, and 2020.

The Company also has granted to certain employees stock options containing market conditions that vest upon the achievement of specified price targets of the Company's share price for a period through December 31, 2024. Vesting is measured based upon the average closing price of the Company's share price for any thirty consecutive trading days, subject to certain service requirements. Stock compensation cost is expensed on a straight-line basis over the derived service period for each stock price target within the award, ranging from approximately 4.0 to 4.6 years. The Company accelerates expense when a stock price target is achieved prior to the derived service period. The Company does not reverse expense recognized if the share price target(s) are ultimately not achieved but expense is reversed when a stock award recipient has a break in service prior to the completion of the derived service period. For each of the three months ended June 30, 2021, and 2020, the Company recorded a de minimis amount of share-based compensation expense, respectively related to these stock options containing market conditions. During the six months ended June 30, 2021, 150,000 stock options containing market conditions were forfeited with a weighted average exercise price of $2.01. As of June 30, 2021, there were 450,000 outstanding stock options containing market conditions with a weighted average exercise price of $2.01. As of June 30, 2021, there was $0.2 million of unrecognized compensation costs related to stock options containing market conditions, which is expected to be recognized over a weighted-average period of 2.67 years.

10. Loss per share

Basic and diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss (in thousands)	$ (16,182)	$ (19,534)	$ (29,581)	$ (39,762)
Denominator:				
Weighted average shares used in calculating net loss per share — basic and diluted (in thousands)	35,707	27,791	34,899	27,730
Net loss per share — basic and diluted	$ (0.45)	$ (0.70)	$ (0.85)	$ (1.43)

For both the three and six months ended June 30, 2021 there were 6,720,598 shares of common stock related to stock options and 125,355 shares of common stock related to RSUs excluded from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive.

For the three months ended June 30, 2020, 7,717,184 shares of common stock related to stock options and 474,923 shares of common stock related to RSU's were excluded from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive.

11. Defined Contribution Plan

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

Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Cyclerion contributions to the plan are at the sole discretion of the board of directors. Currently, Cyclerion provides a matching contribution of 75% of the employee's contributions, up to $6,000 annually.

Included in compensation expense is a de minimis amount and approximately $0.2 million related to the defined contribution 401(k) Savings Plan for the three and six months ended June 30, 2021, respectively and approximately $0.1 million and $0.4 million for the three and six months ended June 30, 2020, respectively.

12. Workforce Reduction

2019 Workforce Reduction

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

The workforce reduction was substantially completed during the year ended December 31, 2019, in which the Company recorded approximately $2.8 million of severance and benefits costs. The workforce reduction was finalized during the three months ended March 31, 2020, in which the Company recorded approximately $0.2 million in additional severance and benefits costs.

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

	Amounts accrued at December 31, 2019	Charges	Amount paid	Adjustments	Amounts accrued at June 30, 2020
October 2019 workforce reduction	$ 2,009	$ 158	$ 2,085	$ (30)	$ 52
Total	$ 2,009	$ 158	$ 2,085	$ (30)	$ 52

2020 Workforce Reduction

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

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

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

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

	Amounts accrued at December 31, 2020	Charges	Amount paid	Adjustments	Amounts accrued at June 30, 2021
2020 workforce reduction	$ (3,640)	$ (858)	$ 3,859	$ —	$ (639)
Total	$ (3,640)	$ (858)	$ 3,859	$ —	$ (639)

13. License Agreement

Akebia License Agreement

On June 3, 2021, the Company and Akebia entered into a License Agreement (the "License Agreement") relating to the exclusive worldwide license by the Company to Akebia of our rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing the pharmaceutical compound known as praliciguat and other related products and forms thereof enumerated in the License Agreement (collectively, the "Products"). Pursuant to the License Agreement, Akebia will be responsible for all future research, development, regulatory, and commercialization activities for the Products.

Akebia paid a $3.0 million up-front payment to the Company upon signing of the License Agreement and the Company is eligible to receive additional milestone cash payments of up to $12.0 million in the next 18 months. Further milestone cash payments by Akebia are scheduled in the License Agreement based on the initiation of phase 3 clinical trials in the U.S. for Products for first and second indication, for FDA approvals, for approvals in certain other major markets, and for certain sales milestones. In addition to these cash milestone payments, Akebia will pay the Company tiered royalty payments on net sales in certain major markets at percentages ranging from the mid-single digits to the high-teens, subject to certain reductions and offsets.

Pursuant to the License Agreement, the Company determined the License Agreement represents a service arrangement under the scope of ASC 606. Given the reversion of the rights under the License Agreement represents a penalty in substance for a termination by Akebia, the contract term would be the stated term of the License Agreement.

The Company determined that the grant of license to our patents and trademarks, know how transfer, the assignment of regulatory submissions and trademarks and additional knowledge transfer assistance obligations represent a single promise and performance obligation to be transferred to Akebia over time due to the nature of the promises in the contract. The provision of development materials on hand was identified as a separate performance obligation. However, it is immaterial in the context of the contract as the development materials are low value and do not have an alternative use to us.

The consideration related to sales-based milestone payments, including royalties, will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license. The Company will re-evaluate the probability of achievement of the milestones and any related constraints each reporting period.

The Company did not have any accounts receivable balances due from Akebia as of June 30, 2021.

14. Subsequent Events

The Company has evaluated all events and transactions that occurred after the balance sheet date through the date the condensed consolidated financial statements were issued and determined that there were no such events requiring recognition or disclosure in the condensed consolidated financial statements.

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

Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited consolidated financial statements and the corresponding notes included in this Quarterly Report on Form 10-Q, as well as the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those referenced or set forth under "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" in Item 1A of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

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

We operate in one reportable business segment—human therapeutics.

Financial Overview

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

CNS assets. The core of our portfolio is CY6463, an orally administered CNS-penetrant sGC stimulator that is being developed as a symptomatic and potentially disease-modifying therapy for CNS diseases associated with cognitive impairment. Nitric oxide-sGC-cGMP is a fundamental CNS signaling network, but it has not yet been leveraged for its full therapeutic potential. CY6463 enhances the brain's natural ability to produce cGMP, an important second messenger in the CNS, by stimulating sGC, a key node in the NO-sGC-cGMP pathway. This pathway is critical to basic CNS functions, and deficient NO-sGC-cGMP signaling is believed to play an important role in the pathogenesis of many CNS diseases. Agents that stimulate sGC to produce cGMP may compensate for deficient NO signaling.

In January 2020, we announced positive Phase 1 study results that provided the foundation for continued development of CY6463. The Phase 1 healthy participant study results indicate that CY6463 was well tolerated. Pharmacokinetic (PK) data, obtained from both blood and cerebral spinal fluid (CSF), support once-daily dosing with or without food and demonstrated CY6463 penetration of the blood-brain-barrier with CSF concentrations expected to be pharmacologically active.

In October 2020, we announced positive topline results from our CY6463 Phase 1 translational pharmacology study in healthy elderly participants. Treatment with CY6463 for 15 days in this 24-subject study confirmed and extended results seen in the earlier first-in-human Phase 1 study: once-daily oral treatment demonstrated blood-brain-barrier penetration with expected CNS exposure and target engagement. Results also showed significant improvements in neurophysiological and objective performance measures as well as in inflammatory biomarkers associated with aging and neurodegenerative diseases. CY6463 was safe and generally well tolerated in this study. Significant effects on cerebral blood flow and markers of bioenergetics were not observed in this study of healthy elderly participants. We believe that these results, together with nonclinical data, support continued development of CY6463 as a potential new medicine for serious CNS diseases.

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

Our next-generation CNS asset, CY3018, is a differentiated CNS-penetrant sGC with greater CSF-to-plasma exposure relative to CY6463 based on nonclinical studies. CY3018 is intended to expand the potential of sGC stimulation for the treatment of disorders of the CNS.

Non-CNS assets. We have other assets that are outside of our current strategic focus. These non-core assets are not being internally developed at this time and, with the exception of praliciguat are available for licensing to a third-party partner. *Praliciguat* is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into a License Agreement with Akebia relating to the exclusive worldwide license to Akebia of our rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing the pharmaceutical compound praliciguat and other related products and forms thereof enumerated in such agreement. *Olinciguat* is an orally administered, once-daily, vascular sGC stimulator that was evaluated in a Phase 2 study of participants with sickle cell disease. We released topline results from this study in October 2020.

The following table summarizes our research and development expenses, employee and facility related costs allocated to research and development expense, and discovery and pre-clinical phase programs, for the three and six months ended June 30, 2021, and 2020. The product pipeline expenses relate primarily to external costs associated with nonclinical studies and clinical trial costs, which are presented by development candidate.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Product pipeline external costs:				
CY6463	2,884	1,500	4,050	2,838
CY3018	606	—	606	—
Olinciguat	74	1,635	240	4,261
Praliciguat	54	79	(414)	215
Discovery research	—	189	700	202
Total product pipeline external costs	3,618	3,403	5,182	7,516
Personnel and related internal costs	2,488	6,738	6,312	14,474
Facilities and other	5,948	3,653	8,652	8,629
Total research and development expenses	$ 12,054	$ 13,794	$ 20,146	$ 30,619

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

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

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

- The full impact of COVID-19 pandemic continues to develop and could continue to adversely affect our programs and operations, including our clinical trials, and corporate development and

other activities. Cyclerion works closely with its clinical trial sites and investigators to deliver trials in a manner consistent with the safety of study participants and healthcare professionals.

- The duration of clinical trials may vary substantially according to the type and complexity of the product candidate and may take longer than expected.
- The United States FDA and comparable agencies outside the United States. impose substantial and varying requirements on the introduction of therapeutic pharmaceutical products, which typically require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures.
- Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.
- The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a product candidate and are difficult to predict.
- The costs, timing and outcome of regulatory review of a product candidate may not be favorable, and, even if approved, a product may face post-approval development and regulatory requirements.
- The emergence of competing technologies and products and other adverse market developments may reduce or eliminate the potential value of our pipeline.

As a result of the factors listed in the “Risk Factors” section in Item 1A of our annual report on Form 10-K for the fiscal year ended December 31, 2020, and elsewhere in this Quarterly Report on Form 10-Q, we are unable to determine the duration and costs to complete current or future nonclinical and clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the data from the studies of each product candidate, the competitive landscape and ongoing assessments of such product candidate’s commercial potential.

General and Administrative Expense. General and administrative expense consists primarily of compensation, benefits and other employee-related expenses for personnel in our administrative, finance, legal, information technology, business development, and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting and legal services. Certain costs associated with our separation from Ironwood are included in these expenses. We record all general and administrative expenses as incurred.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of expenses during the reported periods. We base our estimates on our historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from our estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

We believe that our application of accounting policies requires significant judgments and estimates on the part of management and is the most critical to aid in fully understanding and evaluating our reported financial results. Our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, of the consolidated financial statements elsewhere in this Quarterly Report on Form 10-Q.

All research and development expenses are expensed as incurred. We defer and capitalize nonrefundable advance payments we make for research and development activities until the related goods are received or the related services are performed. See Note 2, *Summary of Significant Accounting Policies*, of the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

The expenses reflected in the consolidated financial statements may not be indicative of revenue and expenses that will be incurred by us in the future. The following discussion summarizes the key factors we believed are necessary for an understanding of our consolidated financial statements.

Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenues:								
Revenue from license agreement	$ 3,000	$ —	$ 3,000	100%	$ 3,000	$ —	$ 3,000	100%
Revenue from development agreement	$ —	$ —	$ —	100%	$ 62	$ —	$ 62	100%
Revenue from related party	$ —	$ 749	$ (749)	(100)%	$ —	$ 1,763	$ (1,763)	(100)%
Total revenues	$ 3,000	$ 749	$ 2,251	301%	$ 3,062	$ 1,763	$ 1,299	74%
Cost and expenses:								
Research and development	12,054	13,794	(1,740)	(13)%	20,146	30,619	(10,473)	(34)%
General and administrative	6,241	6,627	(386)	(6)%	11,606	13,518	(1,912)	(14)%
(Gain) / loss on lease modification and termination	881	—	881	100%	881	(2,113)	2,994	(142)%
Total cost and expenses	19,176	20,421	(1,245)	(6)%	32,633	42,024	(9,391)	(22)%
Loss from operations	(16,176)	(19,672)	3,496	(18)%	(29,571)	(40,261)	10,690	(27)%
Interest and other income, net	(6)	138	(144)	(104)%	(10)	499	(509)	(102)%
Net loss	$ (16,182)	$ (19,534)	$ 3,352	(17)%	$ (29,581)	$ (39,762)	$ 10,181	(26)%

Revenues. As of January 2021, revenues earned from the services performed under the Development Agreement for Ironwood, are not considered to be related party revenues (See Note 3). The increase in revenue of approximately $2.3 million for the three months ended June 30, 2021, compared to the three months ended June 30, 2020, can be attributed to the revenue from the License Agreement, which was executed in June 2021, offset by a decrease in revenue generated from services performed under the Development Agreement, which ended on March 31, 2021.

The increase in revenue of approximately $1.3 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 can be attributed to the revenue from the License Agreement, offset by a decrease in revenue generated from services performed under the Development Agreement.

Research and development expense. The decrease in research and development expense of approximately $1.7 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020 was driven by a decrease of approximately $4.2 million in salaries, stock-based compensation and other employee-related expenses primarily due to lower average headcount, partially offset by a net increase of approximately $2.3 million in facilities and operating costs allocated to research and development primarily due to $4.2 million of non-cash write off of leasehold improvements, and $1.9 million reduction in the Company's total leased premises cost, and a net increase of approximately $0.2 million in external research costs. The net increase in external research costs was primarily due to increases of approximately $1.4 million associated with the startup of CY6463 studies, CIAS and ADv, in Q2'21, and approximately $0.6 million for CY3018 costs, offset by a decrease of $1.6 million related to olinciguat due to the completion of the STRONG-SCD study, with topline data read out on October 14, 2020, and a decrease of approximately $0.2 million in discovery research.

The decrease in research and development expense of approximately $10.5 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 was driven by a decrease of approximately $8.2 million in salaries, stock-based compensation, and other employee-related expenses primarily due to lower average headcount, a decrease of approximately $4.2 million in facilities and operating costs, and a net decrease of approximately $2.3 million in external research costs, partially offset by an increase due to $4.2 million of non-cash write-off of leasehold improvements. The net decrease in external research costs was primarily due to decreases over the periods of approximately $4.0 million related to olinciguat and $0.6 million related to praliciguat studies, due to the completion of both studies, partially offset by an increase of approximately $1.2 million in startup costs for CY6463 studies in CIAS and ADv, an increase of approximately $0.6 million associated with CY3018 and an increase of approximately $0.5 million in discovery research.

General and administrative expense. The decrease in general and administrative expenses of approximately $0.4 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020 was primarily driven by decreases of approximately $1.3 million in salaries, stock-based compensation and other employee-related expenses due to lower average headcount, and a decrease of approximately $1.2 million in facilities and operating costs, partially offset by an increase of approximately $2.1 million of non-cash write off of leasehold improvements.

The decrease in general and administrative expenses of approximately $1.9 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 was primarily driven by a decrease of approximately $2.5 million in salaries, stock-based compensation and other employee-related costs due to lower average headcount, a decrease of approximately $1.1 million in facilities and operating costs, and approximately $0.4 million in professional services, partially offset by $2.1 million of non-cash write off of leasehold improvements.

(Gain) loss on lease modification and termination. The loss on lease modification and termination of approximately $0.9 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020, which is related to the Lease Termination of the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on April 30, 2021. (see Note 8 to the Condensed Consolidated Financial Statements).

The loss on lease modification and termination of approximately $0.9 million for the six months ended June 30, 2021 is related to the Lease Termination of the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on April 30, 2021, compared to the gain on lease modification and termination of $2.1 million in the six months ended June 30, 2020 related to the Lease Amendment of the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on February 28, 2020 (see Note 8 to the Condensed Consolidated Financial Statements).

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

Interest and other income, net decreased by approximately 0.5 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 due to a decrease of approximately $0.3 million in interest income driven by a lower cash balances and lower interest rates, partially offset by a decrease of approximately $0.2 million in net sublease income.

Liquidity and Capital Resources

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

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

On July 29, 2020, we closed on a private placement of 6,062,500 shares of our common stock, pursuant to a Common Stock Purchase Agreement, for total gross proceeds of approximately $24.3 million. There were no material fees or commissions related to the transaction. The Company intends to use the proceeds to fund working capital and other general corporate purposes.

On September 3, 2020, the Company entered into the Sales Agreement with Jefferies with respect to the ATM Offering under the Shelf. Under the ATM Offering, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Jefferies as its sales agent. The Company will pay to Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. During the three and six months ended June 30, 2021, the Company sold 3,351,559 shares of common stock for net proceeds of $12.5 million under the ATM Offering.

On June 7, 2021, we closed on a private placement of 5,735,988 shares of our common stock, pursuant to a Common Stock Purchase Agreement, for total gross proceeds of approximately $18 million. There were no material fees or commissions related to the transaction. The Company intends to use the proceeds to fund working capital and other general corporate purposes.

Our ability to continue to fund our operations and meet capital needs will depend on our ability to generate cash from operations and access to capital markets and other sources of capital, as further described below. We anticipate that our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures and other general corporate purposes.

On June 30, 2021, we had approximately $70.4 million of unrestricted cash and cash equivalents. Our cash equivalents include amounts held in U.S. government money market funds. We invest cash in excess of immediate requirements in accordance with our investment policy, which requires all investments held by us to be at least “AAA” rated or equivalent, with a remaining final maturity when purchased of less than twelve months, so as to primarily achieve liquidity and capital preservation.

Going Concern

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

Cash Flows

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

	Six Months Ended June 30,		Change	
	2021	2020	$	%
	(dollars in thousands)			
Net cash used in operating activities	$ (19,964)	$ (43,401)	$ 23,437	(54)%
Net cash provided by (used in) investing activities	$ 1,464	$ (1,421)	$ 2,885	(203)%
Net cash provided by financing activities	$ 30,657	$ 3,664	$ 26,993	737%

Cash Flows from Operating Activities

Net cash used in operating activities was $20.0 million for the six months ended June 30, 2021 compared to $43.4 million for the six months ended June 30, 2020. The decrease in net cash used in operations of $23.4 million primarily relates to a decrease in our net loss of $10.1 million, non-cash leasehold improvement write off of $6.3 million in the current year, the recording of non-cash loss on lease termination of $0.9 million in the current year and non-cash gain on lease modification of $2.1 million in prior year, and a decrease in working capital accounts of $8.4 million, partially offset by a decrease of stock-based compensation and other non-cash items of $4.4 million.

Cash Flows from Investing Activities

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

Cash Flows from Financing Activities

Net cash provided by financing activities was $30.7 million for the six months ended June 30, 2021 compared to $3.7 million for the six months ended June 30, 2020. The increase of $27.0 million was the result of cash received from the June 2021 Equity Private Placement of $18 million, net proceeds from the ATM Offering of $12.5 million, partially offset by the cash received from the short-term note payable of $3.5 million in 2020.

Debt – Paycheck Protection Program

On April 21, 2020, we received loan proceeds in the amount of approximately $3.5 million pursuant to a promissory note agreement (the "Promissory Note") with a bank under the Paycheck Protection Program ("PPP"), of which certain key terms were adjusted by the Paycheck Protection Program Flexibility Act ("PPPFA"). The Promissory Note has an initial loan maturity of April 20, 2022, a stated interest rate of 1.0% per annum, and has payments of principal and interest that are due monthly after an initial deferral period where interest accrues, but no payments are due. Under the PPPFA, the initial deferral may be extended from six up to ten months and the loan maturity may be extended from two to five years. The Promissory Note provides for customary events of default, including, among others, those relating to failure to make payment when due and breaches of representations. We may prepay the principal of the Promissory Note at any time without incurring any prepayment charges. The loan is subject to all the terms and conditions applicable under the PPPFA and is subject to review by the Small Business Association for compliance with program requirements.

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

Funding Requirements

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

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

Because of the many risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our expenses will fluctuate, and our future funding requirements will depend on, and could increase or decrease significantly as a result of many factors, including the:

- scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- costs, timing and outcome of regulatory review of our product candidates;

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, outstanding equity ownership may be materially diluted, and the terms of securities sold in such transactions could include liquidation or other preferences that adversely affect the rights of holders of common stock. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Commitments and Obligations

Tax-related Obligations

We exclude assets, liabilities or obligations pertaining to uncertain tax positions from our summary of contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of June 30, 2021, we had no uncertain tax positions.

Other Funding Commitments

As of June 30, 2021, we had, and continue to have, several ongoing studies in various clinical trial stages. Our most significant clinical trial spending is with clinical research organizations, or CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any significant cancellation penalties.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance.

New Accounting Pronouncements

For a discussion of new accounting pronouncements see Note 2, *Summary of Significant Accounting Policies*, of the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Because there are inherent limitations in all control systems, a control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. ***Legal Proceedings***

We are not a party to any material legal proceedings at this time. From time to time we may be subject to various legal proceedings and claims, which may have a material adverse effect on our financial position or results of operations.

Item 1A. ***Risk Factors***

You should carefully review and consider the information regarding certain factors which could materially affect our business, financial condition or future results set forth under the heading “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Item 5. ***Other Information***

Not applicable.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

Exhibit No.	Description
10.1	Common Stock Purchase Agreement, dated as of June 3, 2021, by and between Cyclerion Therapeutics, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 to Registration Statement on Form S-3 filed on June 16, 2021 (File No. 333-257145)).
10.2*	License Agreement, dated as of June 3, 2021, by and between Cyclerion Therapeutics, Inc. and Akebia Therapeutics, Inc.
31.1	Certificate of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certificate of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of Chief Executive Officer (Principal Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certificate of Chief Financial Officer (Principal Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File.

* Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type that the Registrant treats as private or confidential.

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 Hecht
Name: Peter M. Hecht
Title: *Chief Executive Officer (Principal Executive Officer)*

By: /s/ Anjeza Gjino
Name: Anjeza Gjino
Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

Date: July 29, 2021

Exhibit 10.2

Certain information has been excluded from this agreement (indicated by "[***]") because such information is both not material and the type that the registrant treats as private or confidential.

CONFIDENTIAL

LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is made effective as of June 3, 2021 (the "**Effective Date**") by and between Cyclerion Therapeutics, Inc., a Massachusetts corporation ("**Cyclerion**") and Akebia Therapeutics, Inc., a Delaware corporation ("**Akebia**") (each of Cyclerion and Akebia being a "**Party**", and collectively, the "**Parties**").

WHEREAS, Cyclerion controls certain intellectual property rights with respect to the Licensed Compounds (as defined herein) and Products (as defined herein) in the Territory (as defined herein); and

WHEREAS, Cyclerion wishes to grant to Akebia, and Akebia wishes to be granted, an exclusive license under such intellectual property rights to Exploit (as defined herein) Licensed Compounds and Products in the Territory, in each case, in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article 1
DEFINITIONS

The following terms, whether used in the singular or the plural, shall have the meanings designated to them under this Article unless otherwise specifically indicated.

1.1 "**Additional Development Materials**" has the meaning set forth in Section 5.5.

1.2 "**Affiliate**" means, with respect to a Party, any Person controlled by, controlling, or under common control with such Party. For purposes of this Section 1.2 only, "control" and, with corresponding meanings, the terms "controlled by," "controlling," and "under common control with" means (a) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities, participating profit interest, or other ownership interests of a legal entity, or (b) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance.

1.3 "**Agreement**" has the meaning set forth in the preamble hereto.

1.4 "**Akebia**" has the meaning set forth in the preamble hereto.

1.5 "**Akebia Indemnitees**" has the meaning set forth in Section 12.1.

1.6 "**Akebia Intellectual Property**" means (a) any Know-How Controlled by Akebia or any of its Affiliates as of the effective date of termination of this Agreement that is used in the Exploitation of any Product as of such effective date of termination, and (b) any Patents Controlled by Akebia or any of its Affiliates as of the effective date of termination of this Agreement that would be infringed by the Exploitation of any Product.

1.7 "**Akebia Primary Patents**" has the meaning set forth in Section 9.2(b)(i).

1.8 "**Assigned Trademarks**" means the Trademarks set forth on Schedule 1.8.

1.9 "**Business Day**" means any day except (a) Saturday, (b) Sunday, (c) any day that is a federal legal holiday in the U.S., or (d) any day on which banking institutions in the Commonwealth of Massachusetts are authorized or required by law or other governmental action to close.

1.10 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.11 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.12 "**Centralized Approval Procedure**" means the procedure through which a MAA filed with the EMA results in a single marketing authorization valid throughout the European Union.

1.13 "**Clinical Trial**" means a study in humans to obtain information regarding a pharmaceutical or biological product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such product, including a Phase 2 Clinical Trial and a Phase 3 Clinical Trial.

1.14 "**Combination Product**" means a Product that is comprised of or contains a Licensed Compound as an active ingredient together with one or more other active ingredients and is sold either as a fixed dose or as separate doses but in any event for a single price.

1.15 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Product, including activities related to pricing and reimbursement (including obtaining and maintaining Pricing Approval), marketing, promoting, distributing, and importing, and interacting with Regulatory Authorities regarding any of the foregoing, but excluding activities directed to Development, Manufacturing, and Medical Affairs. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.16 "**Commercial Sublicense Income**" means any consideration received by Akebia or any of its Affiliates solely on the basis of sales of the Products by any Significant Sublicensee in any of the Major Countries (and sales by such Significant Sublicensee in any other countries or other jurisdictions in the Territory to the extent included in the grant of such a sublicense for any Major Country), including [***]. Notwithstanding any provision to the contrary set forth in this Agreement, Commercial Sublicense Income shall exclude [***]. To the extent that Akebia or its Affiliates receives any amounts not solely related to the sale of the Products, then the "Commercial Sublicense Income" attributable to the Products will be apportioned between [***].

1.17 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective or activity, [***].

1.18 "**Confidential Information**" means, subject to Section 10.1, (a) the terms of this Agreement and (b) with respect to each Party, Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other information that may be disclosed by one Party to the other Party pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the that certain Confidential Disclosure Agreement between the Parties, [***]), regardless of whether such information is specifically designated as confidential or proprietary and regardless of whether such information is in written, oral, electronic, or other form.

1.19 "**Control**" means, with respect to any item of Know-How, Patent, or any intellectual property right, that a Party owns or has a license to such item or right and has the ability to grant to the other Party a license or sublicense under such item or right as provided for in this Agreement without breaching or otherwise violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Know-How, Patent, or any intellectual property right that, (i) prior to the consummation of an acquisition of such Party (whether by merger, stock purchase, or purchase of assets), is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such acquisition, or (ii) is generated or discovered after such an acquisition independent of this Agreement by employees or consultants of the Third Party that becomes an Affiliate of a Party who conduct no activities under this Agreement and who have no access to the Confidential Information disclosed or generated under this Agreement, unless (A) prior to the consummation of such acquisition, such acquired Party or any of its Affiliates also Controlled such Know-How, Patent, or intellectual property right, or (B) after the consummation of such acquisition, such acquired Party or any of its Affiliates determines to use or uses any such Know-How, Patent, or intellectual property right in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((A) and (B)), such Know-How, Patent, or intellectual property right, as applicable, will be "Controlled" by such Party for purposes of this Agreement. "**Controlled**" and "**Controlling**" have corresponding meanings.

1.20 "**Control Transferring Patent**" has the meaning set forth in Section 9.2(a)(i).

1.21 "**Convicted Entity**" has the meaning set forth in Section 11.3(d).

1.22 "**Convicted Individual**" has the meaning set forth in Section 11.3(d).

1.23 "**Cover**" means, when used to refer to the relationship between a particular Patent and particular subject matter, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in, or is otherwise claimed by, such Patent.

1.24 "**Cyclerion**" has the meaning set forth in the preamble hereto.

1.25 "**Cyclerion Competing Product**" means any pharmaceutical product that contains [***].

1.26 "**Cyclerion Indemnitee**" has the meaning set forth in Section 12.2.

1.27 "**Cyclerion Indication**" means [***].

1.28 "**Cyclerion Intellectual Property**" means the Cyclerion Patents and Cyclerion Know-How and Cyclerion's interest in the Joint Intellectual Property Rights.

1.29 "**Cyclerion Know-How**" means any Know-How, other than Joint Know-How, Controlled by Cyclerion or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Exploitation of any Licensed Compound or Product.

1.30 "**Cyclerion Patent**" means any Patent, other than a Joint Patent, Controlled by Cyclerion or its Affiliates as of the Effective Date or [***].

1.31 "**Debarred Entity**" has the meaning set forth in Section 11.3(b).

1.32 "**Debarred Individual**" has the meaning set forth in Section 11.3(a).

1.33 "**Development**" means all internal and external research, development, and regulatory activities regarding the Licensed Compound or the Products. This includes (a) research, preclinical testing, toxicology, route of synthesis, non-clinical activities, formulation, and clinical studies of such Licensed Compound or Products; and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain or maintain Regulatory Approval of a Product. Development also includes development and regulatory activities for additional forms, formulations or Indications for a Product, including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after a Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved Indication including post-marketing studies and observational studies, if required by any Regulatory Authority in any country in the Territory to maintain Regulatory Approval for a Product in such country, but Development excludes all activities directed to Manufacturing, Medical Affairs, and Commercialization. "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.34 "**Development Materials**" has the meaning set forth in Section 5.4.

1.35 "**Development Plan**" has the meaning set forth in Section 3.1.

1.36 "**Dollars**" means U.S. dollars.

1.37 "**Drug Product**" means that certain finished Product manufactured [***].

1.38 "**Effective Date**" has the meaning set forth in the preamble hereto.

1.39 "**EMA**" means the European Medicine Agency or any successor agency thereto or authority having substantially the same function.

1.40 "**E.U. Regulatory Approval**" means (a) receipt of Regulatory Approval by the EMA through the Centralized Approval Procedure or (b) receipt of Regulatory Approval from the applicable Regulatory Authorities in [***] Major European Countries.

1.41 "**European Union**" or "**E.U.**" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto; *provided* that for the purposes of this Agreement, the European Union shall be deemed to include the United Kingdom.

1.42 "**Excluded Entity**" has the meaning set forth in Section 11.3(c).

1.43 "**Excluded Individual**" has the meaning set forth in Section 11.3(c).

1.44 "**Excluded Indication**" means [***].

1.45 "**Executive Officer**" means, with respect to Cyclerion, its Chief Executive Officer and, with respect to Akebia, its Chief Executive Officer.

1.46 "**Existing Drug Substance**" means the existing inventory of praliciguat drug substance that Cyclerion has on hand as of the Effective Date, [***].

1.47 "**Exploit**" means to Develop, Manufacture, perform Medical Affairs with respect to, Commercialize, and otherwise make, use, sell, offer for sale, or import.

1.48 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto or authority having substantially the same function.

1.49 "**FDA's Disqualified/Restricted List**" has the meaning set forth in Section 11.3(d).

1.50 "**FFDCA**" means the U.S. Federal Food, Drug, and Cosmetics Act (21 U.S.C. Section 301 *et seq.*), as amended from time to time, together with any rules, regulations and requirements promulgated thereunder.

1.51 "**Field**" means the treatment, prevention, or diagnosis of any diseases or conditions in humans.

1.52 "**First Commercial Sale**" means, with respect to a Product and a country or other jurisdiction in the Territory, the first *bona fide*, arm's length sale of such Product in such country after Regulatory Approval has been obtained for such Product in such country or other jurisdiction. First Commercial Sale excludes any sale or other distribution of a Product for Clinical Trial or other Development purposes, early access programs (such as to provide patients with such Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

1.53 "**GAAP**" means U.S. generally accepted accounting principles (or such accounting principles adopted by Akebia for the calculation of Net Sales, as applicable), consistently applied.

1.54 "**Generic Product**" means, with respect to a Product and a particular country, any pharmaceutical product that (a) is sold in such country by a Third Party that is not a Sublicensee of Akebia or its Affiliates, or any of their Sublicensees, under a Regulatory Approval granted by the applicable Regulatory Authority to a Third Party, (b) contains as an active ingredient the same active ingredient as such Product, and (c) is approved in part in reliance on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Product (i) in the U.S., pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), or (ii) in any other country or jurisdiction in the Territory, pursuant to all equivalents of any of the foregoing. Notwithstanding the foregoing, [***].

1.55 "**Good Clinical Practices**" or "**GCP**" means the then-current standards, practices and procedures for designing, conducting, recording and reporting Clinical Trials as required by applicable Regulatory Authorities or applicable law in the relevant jurisdiction of such Clinical Trial, including, in the U.S., those promulgated or endorsed by the FDA and in the E.U. those required by the EMA under comparable applicable laws in the European Union, as set forth in the guidelines

entitled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” and including related regulatory requirements imposed by the FDA or EMA, as applicable.

1.56 “**Good Manufacturing Practices**” or “**GMP**” means the then-current good manufacturing practices applicable from time to time to the Manufacturing of the Licensed Compounds or the Products or any intermediate thereof pursuant to applicable law in the jurisdiction of Manufacture, including in the U.S. those required by the FDA, as set forth in the FFDCA and the regulations promulgated thereunder, and in the E.U. those required by the EMA under comparable applicable laws in the European Union, for the manufacture, testing and release of pharmaceutical materials, as they may be updated from time to time, and applicable quality guidelines promulgated under the ICH (International Council for Harmonization).

1.57 “**IND**” means (a) an Investigational New Drug Application as defined in the FFDCA and applicable regulations promulgated thereunder by the FDA, the filing of which is necessary to commence a Clinical Trial, and equivalent filings with Regulatory Authorities outside the U.S., including the EMA and PMDA, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.58 “**Indemnitee**” has the meaning set forth in Section 12.3.

1.59 “**Indemnitor**” has the meaning set forth in Section 12.3.

1.60 “**Indication**” means each separate and distinct disease, disorder, or condition. Notwithstanding any provision to the contrary set forth in this Agreement: (a) with respect to a Product, if such Product has received Regulatory Approval for which at least one adequate and well-controlled Clinical Trial is required to support the addition of a disease, disorder, or condition to the indication statement on the Regulatory Authority-approved labeling for such Product, such approval shall be deemed to be Regulatory Approval for a new Indication; (b) each of the following will be treated as the same Indication and not a distinct Indication: (i) the treatment of a disease, disorder, or condition in a particular patient population and the treatment of the same disease, disorder, or condition in another population (*e.g.*, adult population and pediatric population); (ii) different subtypes or lines of therapy for the same disease, disorder, or condition; and (iii) different doses or dosing schedules for the same disease, disorder, or condition; and (c) each of the following will be treated as distinct Indications: [***].

1.61 “**Initial Supply**” has the meaning set forth in Section 5.1.

1.62 “**Initial Supply Notice Date**” has the meaning set forth in Section 5.1.

1.63 “**Initiating Party**” has the meaning set forth in Section 9.4(d).

1.64 “**Initiation**” means, with respect to a given Clinical Trial, the administration of the first dose of a Product to the first duly screened and enrolled subject in accordance with the study protocol for such Clinical Trial.

1.65 “**Joint Intellectual Property Rights**” has the meaning set forth in Section 9.1(b).

1.66 “**Joint Know-How**” has the meaning set forth in Section 9.1(b).

1.67 “**Joint Patents**” has the meaning set forth in Section 9.1(b).

1.68 "**Know-How**" means any (a) proprietary information or materials, including records, improvements, modifications, techniques, assays, processes, methods, utilities, formulations, compositions of matter, articles of manufacture, materials (including chemical or biological materials), creation, discovery or finding, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) any physical embodiments of any of the foregoing.

1.69 "**Knowledge**" means the actual knowledge, as of the Effective Date, of the individuals of Cyclerion [***].

1.70 "**Licensed Compound**" means (a) the pharmaceutical compound known as praliciguat, which has the chemical structure set forth on Schedule 1.70, and (b) any metabolite, salt, ester, hydrate, solvate, isomer, enantiomer, free acid form, free base form, crystalline form, co-crystalline form, amorphous form, pro-drug (including ester pro-drug) form [***], racemate, polymorph, chelate, stereoisomer, tautomer, or optically active form of any of the foregoing.

1.71 "**MAA**" or "**Marketing Authorization Application**" means (a) a New Drug Application as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of any country in the European Union with respect to the mutual recognition or any other national approval procedure, and (b) all supplements and amendments to any of the foregoing.

1.72 "**Major Countries**" means [***].

1.73 "**Major European Countries**" means [***].

1.74 "**Manufacture**" and **"Manufacturing**" means, with respect to any product (including active pharmaceutical ingredient and other intermediate or material contained therein), any and all activities related to the manufacture of such product, including qualification, validation and scale-up, pre-clinical, clinical and commercial manufacture, packaging, labeling, filling, finishing, assembly, processing, in-process and finished product testing, release of such product or any component or ingredient thereof, quality assurance, quality control and audit activities related to manufacturing, testing and release of such product, ongoing stability tests, storage, shipping, supply or storage of such product (or any components or process steps involving such product or any companion diagnostic), placebo or comparator agent, as the case may be, product characterization, technical support activities, and regulatory activities related to any of the foregoing, but excluding any activities directed to Development, Medical Affairs, and Commercialization of such product.

1.75 "**Manufacturing Process**" means the process for the Manufacture of the Licensed Compounds and Products, including the then-current process for the Manufacture of the Licensed Compounds and Products.

1.76 "**Manufacturing Process Improvements**" means any [***].

1.77 "**Manufacturing Process Patents**" means any Patents Controlled by Akebia that Cover any Manufacturing Process Improvements.

1.78 "**Manufacturing Transfer Plan**" has the meaning set forth in Section 5.7.

1.79 "**Medical Affairs**" means, with respect to a Product, any and all activities performed by or on behalf of a Party's or its Affiliates' medical affairs departments interacting with physicians or other healthcare professionals who utilize or conduct research related to a drug or biological product, including: supporting continuing medical education and other medical programs and communications; development, publication, and dissemination of publications; development and fulfillment of medical information responses; development and execution of disease awareness education including symposia and digital education initiatives; sponsorship and booth exhibition at key congresses; conducting health economic, burden of illness/disease, natural history and real world evidence studies;; supporting educational fellowships and research grants, supporting external research efforts such as scientific research agreements and investigator initiated trials (following Regulatory Approval); medical resourcing, training and allocation; medical and scientific platform, content development, publications, and communications; conducting appropriate activities involving opinion leaders, including communications and engagement; conducting medical science liaison activities; advisory boards (to the extent related to medical affairs or clinical guidance) and conducting advisory board meetings or other consultant programs; establishing patient registries and expanded access programs; post-approval investigator initiated trials or scientific research agreements; life cycle management activities and clinical research and investigator initiated research (IIR), expressly excluding activities directed to Development, Manufacturing, and Commercialization.

1.80 [***]

1.81 [***]

1.82 [***]

1.83 [***]

1.84 "**Net Sales**" means [***].

1.85 "**New License Agreement**" has the meaning set forth in Section 8.5.

1.86 "**Non-Commercial Sublicense Income**" means any consideration (including in the form of upfront payments, license fees, milestone payments, including any milestone payments for the receipt of Regulatory Approval but excluding [***], and the fair market value of any non-cash consideration as determined in accordance with Section 7.6(c).) received by Akebia or any of its Affiliates from any Significant Sublicensee in consideration for the grant by Akebia or any of its Affiliates of a sublicense to such Significant Sublicensee of any of the rights granted to Akebia under this Agreement with respect to the Licensed Compounds or the Products or under any of the Cyclerion Intellectual Property in any of the Major Countries (and any other countries or other jurisdictions in the Territory to the extent included in the grant of such a sublicense for any Major Country), including [***]. Notwithstanding any provision to the contrary set forth in this Agreement, Non-Commercial Sublicense Income shall exclude [***].

1.87 "**Non-Control Transferring Patent**" has the meaning set forth in Section 9.2(c)(i).

1.88 "**Party**" or "**Parties**" has the meaning set forth in the preamble hereto.

1.89 "**Patent(s)**" means (a) any and all national, regional and international patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, including provisional patent applications, and (b) any renewal, divisional, continuation (in whole or in part), or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents (including utility models, petty patents and design patents) or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.90 "**Patent Challenge**" has the meaning set forth in Section 13.2(c).

1.91 "**Patent Contact**" has the meaning set forth in Section 9.3.

1.92 "**Patent Linkage**" has the meaning set forth in Section 9.2(f).

1.93 "**Patent Term Extension**" has the meaning set forth in Section 9.2(f).

1.94 "**Patent Transfer Date**" means the earlier of [***], and (b) such date that the Parties may agree, following request by Akebia or Cyclerion.

1.95 "**Person**" means any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

1.96 "**Phase 2 Clinical Trial**" means a human clinical trial of a product, which trial the FDA permits to be conducted under an open IND, with the endpoint of evaluating its effectiveness for a particular Indication or Indications in one or more specified doses or its short term tolerance and safety, as well as its pharmacokinetic and pharmacodynamic information in patients with the Indications under study, that is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Trial for such product, and that satisfies the requirements of U.S. federal regulation 21 C.F.R. § 312.21(b) and its successor regulation or equivalents in other jurisdictions.

1.97 "**Phase 3 Clinical Trial**" means a human clinical trial of a product on a sufficient number of patients, which trial the FDA permits to be conducted under an open IND, and that is designed to: (a) establish that the product is safe and efficacious for its intended use; (b) define warnings, precautions, and adverse reactions that are associated with the product in the dosage range to be prescribed; and (c) enable, without additional clinical trials, the submission of an MAA to a Regulatory Authority for the product, and that satisfies the requirements of U.S. federal regulation 21 C.F.R. § 312.21(c) and its successor regulation or equivalents in other jurisdictions.

1.98 "**PMDA**" means the Pharmaceuticals and Medical Devices Agency of Japan or any successor agency thereto or authority having substantially the same function.

1.99 "**Pricing Approval**" means such approval, agreement, determination, or decision establishing prices for a Product that can be charged to consumers or reimbursed by Regulatory Authorities in a country or regulatory jurisdiction where the applicable Regulatory Authorities of such country or regulatory jurisdiction approve or determine the pricing or reimbursement of pharmaceutical products.

1.100 "**Product**" means any pharmaceutical product containing a Licensed Compound, alone or in combination with one or more other active ingredients (including all Combination Products), in any and all forms, presentations, delivery systems, dosages, and formulations.

1.101 "**Product Infringement**" has the meaning set forth in Section 9.4(a).

1.102 "**Reduction Floor**" has the meaning set forth in Section 7.5(e)(iv).

1.103 "**Regulatory Approval**" means, with respect to a country or other jurisdiction in the Territory, any and all approvals (including approval of an MAA), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, and market a Licensed Compound or Product in such country or other jurisdiction, excluding any Pricing Approvals in such country or other jurisdiction (where applicable).

1.104 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory agencies, departments, bureaus, commissions, councils, or other government entities (*e.g.*, the FDA, EMA, and PMDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Development, Manufacture, or Commercialization of pharmaceutical products.

1.105 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or jurisdiction in the Territory other than Patents that (a) prohibit any Person from relying on safety or efficacy data generated by or on behalf of a Party with respect to such Product in an application for Regulatory Approval of a Generic Product, or (b) confer an exclusive Commercialization period during which Akebia or its Affiliates or Sublicensees have the exclusive right to market and sell a Licensed Compound or a Product in such country or jurisdiction, including rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), orphan drug exclusivity, or rights similar thereto outside the U.S.

1.106 "**Regulatory Submissions**" means all (a) applications (including all INDs and MAAs), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to a Licensed Compound or Product.

1.107 "**Residual Knowledge**" has the meaning set forth in Section 10.5.

1.108 "**Restricted Product**" has the meaning set forth in Section 8.8(c).

1.109 "**Royalty Term**" means, with respect to each Product and each country or other jurisdiction in the Territory, the period beginning on the date of [***] in such country or other jurisdiction, and ending on the latest to occur of [***].

1.110 "**Sell-Down Period**" has the meaning set forth in Section 13.3(g).

1.111 "**Significant Sublicensee**" means any Sublicensee to whom Akebia or an Affiliate of Akebia grants a sublicense of any of the rights granted to Akebia in Section 8.1 as permitted under Section 8.4 (a) in any of the Major Countries (and in any other countries or other jurisdictions in the Territory to the extent included in the grant of such a sublicense for any Major Country), and (b) that includes a grant of rights to sell one or more Products on such Sublicensee's own behalf in such Major

Countries and Sublicensee has the right to record such Product sales in its financial statements in accordance with U.S. GAAP or similar accounting standards in countries outside of the U.S..

1.112 "**Sublicensee**" means any Third Party to whom Akebia or an Affiliate of Akebia grants a sublicense of any of the rights granted to Akebia in Section 8.1 as permitted under Section 8.4, but expressly excluding all Third Party Distributors.

1.113 "**Supply Agreement**" has the meaning set forth in Section 5.1.

1.114 "**Term**" has the meaning set forth in Section 13.1.

1.115 "**Territory**" means worldwide.

1.116 "**Third Party**" means any person or entity other than Cyclerion, Akebia, and their respective Affiliates.

1.117 "**Third Party Claims**" has the meaning set forth in Section 12.1.

1.118 "**Third Party Distributor**" means, with respect to a country, any Third Party that purchases its requirements for Products in such country from Akebia or its Affiliates or Sublicensees and is appointed as a distributor to distribute, market, and resell such Product in such country, even if such Third Party is granted ancillary rights to Develop, package, or obtain Regulatory Approval of such Product in order to distribute, market, or sell such Product in such country.

1.119 "**Trademarks**" means any word, name, symbol, color, shape, designation or any combination thereof that functions as an identifier of source or origin, including any trademarks, trade names, trade dress, service marks, domain names, logos, slogans and brandings, registered or unregistered, whether at common law or statutory, and all registrations and applications therefor, and all goodwill associated with the foregoing.

1.120 "**U.S.**" means the United States of America, including its territories and possessions.

1.121 "**Valid Claim**" (a) a claim of any issued and unexpired Patent whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim of a pending Patent application, which claim has not been pending for more than [***] since the earliest date such Patent application is entitled to claim priority, unless and until such claim becomes an issued claim of an issued patent in which case it will again be considered a Valid Claim under the foregoing clause (a).

Article 2
INFORMATION SHARING

2.1 **Good Faith Information Sharing.** The Parties agree that they will cooperate in good faith to share relevant information and expertise regarding the Development (including CMC), Manufacturing, Medical Affairs, and Commercialization of the Product through discussions between appropriate representatives of the Parties as may be arranged from time to time. On an [***] basis, through a presentation to representatives of Cyclerion, Akebia will provide Cyclerion with an update with

respect to the Development, Manufacturing, Medical Affairs, and Commercialization activities that it has performed, or caused to be performed, for the Products in the Field in the Territory on a Major Country-by-Major Country basis since the preceding update and a summary of the key Development, Manufacturing, Medical Affairs, and Commercialization activities that Akebia expects to perform, or caused to be performed, for the Products in the Field in the Territory on a Major Country-by-Major Country basis during the then-current Calendar Year. Following each such [***] meeting, Akebia shall provide to Cyclerion with a written copy of such presentation as was presented by Akebia to the representatives of Cyclerion.

Article 3
DEVELOPMENT

3.1 **Overview of Development**. Subject to the terms and conditions of this Agreement, Akebia shall have sole control over and decision-making authority with respect to the Development of the Licensed Compounds and Products in the Field in the Territory in accordance with this Article 3, including obtaining and maintaining Regulatory Approval therefor.

3.2 **Diligence.** Akebia shall, and shall cause its Affiliates to, perform any and all Development activities under this Agreement in compliance in all material respects with applicable laws and regulations, including as applicable GCP and GMP. Akebia shall use Commercially Reasonable Efforts to [***]. Akebia shall have the right to satisfy its diligence obligations under this Section 3.2 through its Affiliates or Sublicensees. If at any time Cyclerion has a reasonable basis to believe that Akebia is [***].

3.3 **Development Plan**. All Development of the Products in the Territory will be governed by a written development plan, as such development plan may be revised by Akebia in its sole discretion from time to time (the "**Development Plan**"). The initial Development Plan is attached hereto as Schedule 3.3. For the avoidance of doubt, Akebia is under no obligation to provide Cyclerion notice of, or copies of, any changes to the Development Plan.

3.4 **Third Party Contractors.** Akebia may engage any Third Party subcontractor to perform any or all of its obligations hereunder, *provided* that (a) Akebia will (i) remain primarily liable to Cyclerion for the performance of all of its obligations under, and Akebia's compliance with all provisions of, this Agreement, and (ii) be fully responsible and liable for any conduct by any of its subcontractors that would amount to a breach of the terms of this Agreement if performed by Akebia, in each case, to the same extent as if Akebia itself has committed such breach, and (b) the agreement pursuant to which Akebia engages any Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain terms with respect to intellectual property that are consistent with the intellectual property provisions of this Agreement, and (iii) contain obligations of confidentiality and non-use no less stringent that the confidentiality terms of this Agreement.

3.5 **Development Costs.** Except as otherwise provided in this Agreement, Akebia shall be responsible for all of its costs and expenses in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, the Products in the Field in the Territory.

3.6 **Records.** Akebia shall maintain records in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with applicable law, which shall reflect all work done and results achieved in the performance of its Development activities for the Products in the Field in the Territory. Such records shall be retained by Akebia for at least [***]

years after the termination of this Agreement, or for such longer period as may be required by applicable law.

Article 4
REGULATORY MATTERS

4.1 **Transfer of Regulatory Submissions.** [***] following the Effective Date, Cyclerion shall transfer to Akebia all INDs for the Products listed on Schedule 4.1 (unless otherwise agreed by the Parties) and any other Regulatory Submissions for the Licensed Compounds and Products in the Field in the Territory, and in connection with such transfer Cyclerion shall take all actions required to assign, convey, transfer, and deliver to Akebia, all of Cyclerion's rights, title, and interests in and to such Regulatory Submissions (including executing and delivering such endorsements, assignments, and other documents as may be necessary). Without limiting Cyclerion's obligations under this Section 4.1, [***] the Effective Date, Cyclerion will submit to the applicable Regulatory Authorities a letter or other necessary documentation (with copy to Akebia) notifying such Regulatory Authorities of such transfer. Following transfer to Akebia, Akebia shall thereafter be responsible for the maintenance of such INDs and any other Regulatory Submissions for the Licensed Compounds and the Products in the Field in the Territory at its sole cost and expense.

4.2 **Regulatory Responsibilities.** Subject to the terms and conditions of this Agreement, as between the Parties, Akebia shall have sole control over and decision-making authority with respect to, at its own expense, preparing, filing, and maintaining all Regulatory Submissions for Licensed Compounds and Products in the Field in all countries and regulatory jurisdictions of the Territory, including preparing all reports required in connection with the submission of any application for Regulatory Approval. All Regulatory Submissions for the Licensed Compounds and the Products in the Field shall be filed in the name of Akebia or one of its Affiliates or Sublicensees, or in the case of an investigator-sponsored trial, in the name of the investigator or institution conducting the study, and, as between the Parties, Akebia shall sole control over and decision-making authority with respect to all communications and other dealings with the Regulatory Authorities relating to the Licensed Compounds and the Products in the Field in the Territory. As between the Parties, following completion of the assignment and transfer contemplated in Section 4.1, Akebia shall be the legal and beneficial owner of all Regulatory Submissions and Regulatory Approvals for the Licensed Compounds and the Products in the Field in all countries and regulatory jurisdictions of the Territory.

Article 5
MANUFACTURE AND SUPPLY OF PRODUCT AND PRE-CLINICAL MATERIALS

5.1 **Initial Supply of Products**. Unless otherwise agreed to in writing by the Parties, the Parties shall enter into a supply agreement (the "**Supply Agreement**") [***] the Effective Date, which will include the terms set forth in this Article 5 as well as other terms customary for supply arrangements between licensees and licensors pursuant to which licensor receives milestone and royalty payments. Pursuant to the Supply Agreement, Cyclerion [***]. The Parties shall use Commercially Reasonable Efforts to ensure that delivery of the Initial Supply shall occur no later than [***] from the Initial Supply Notice Date, or at such a time agreed upon by the Parties in writing. The term of the Supply Agreement shall conclude [***].

5.2 **Compliance; Warranties**. The Supply Agreement will contain terms and conditions regarding compliance with applicable law and specifications for the Existing Drug Substance and Drug Product, delivery, acceptance, recalls, indemnification, and limitations of liability.

5.3 **Price.** The Initial Supply shall be supplied to Akebia or its designee at Cyclerion's actual fully-burdened Manufacturing [***]. The fully-burdened Manufacturing cost will include [***], solely to the extent incurred after the Effective Date. The approximate cost of the Initial Supply is [***], assuming an Initial Supply as set forth in Schedule 5.3. If Cyclerion becomes aware that the cost of the Initial Supply is anticipated to materially increase from this estimate, then Cyclerion shall promptly provide notice to Akebia of such anticipated cost change and the new estimated cost of the Initial Supply. Promptly thereafter, the Parties will meet and discuss in good faith any steps that either Party may take to mitigate such cost increase.

5.4 **Development Materials**. The Parties acknowledge that, as of the Effective Date, Cyclerion is in the physical possession of that inventory of [***] (collectively, [***] the "**Development Materials**"), in each case, as set forth on Schedule 11.1(u). Promptly after the Effective Date and pursuant to the terms of the Supply Agreement, Cyclerion shall supply Akebia with all Development Materials that Cyclerion controls, including those materials in the possession of Cyclerion's Third Party contract manufacturers, and that are listed on Schedule 11.1(u), at no cost to Akebia, and Cyclerion shall transfer title to Akebia to all such Development Materials in accordance with the terms of the Supply Agreement. Cyclerion hereby agrees to manage any storage, handling, and shipment of such inventory in accordance with Akebia's reasonable written directions and, as applicable, the terms of the Supply Agreement, including by transferring such Development Materials to Akebia or its designee at Akebia's direction.

5.5 **Additional Development Materials**. The Parties acknowledge that as of the Effective Date Cyclerion is in physical possession of that inventory of [***] (the "**Additional Development Materials**"). At any time during the period commencing on the Effective Date and continuing until the date that is [***] thereafter, Akebia may elect to purchase and take delivery of any or all of such inventory, in units that are readily available and at the applicable price set forth on Schedule 11.1(u), by providing written notice to Cyclerion of the Additional Development Materials Akebia elects to purchase and have delivered, and Cyclerion shall deliver such inventory to Akebia or its designee at Akebia's direction, at Akebia's cost and expense, and title to such Additional Development Materials shall transfer to Akebia at the time of delivery. Cyclerion shall use reasonable efforts to manage any storage and handling of all Additional Development Materials in accordance with standard industry practice. Akebia shall reimburse Cyclerion all reasonable costs incurred by Cyclerion or its Affiliates in connection with the storage of such Additional Development Materials during such [***] period until delivery thereof to Akebia, within [***] after receipt of an invoice therefor. Notwithstanding the foregoing, on a material-by-material basis Akebia may waive its option to purchase some or all of such Additional Development Materials by providing written notice of such waiver, and from the date of delivery of such notice Akebia shall no longer reimburse Cyclerion for the costs incurred by Cyclerion or its Affiliates in connection with the storage of such material.

5.6 **Manufacture of Licensed Compounds and Products after Initial Supply**. As between the Parties, after successful supply to Akebia or its designee of all Initial Supply and after the Supply Agreement expires or is terminated, Akebia shall have sole control over and decision-making authority with respect to, at its expense, (a) Manufacturing (or having Manufactured) the Licensed Compounds and Products and (b) Manufacturing (or having Manufactured) [***], and all other intermediates and other precursors of the Licensed Compounds and the Products, solely for the purpose of Manufacturing the Licensed Compounds and the Products for Development and Commercialization in the Field in the Territory by Akebia and its Affiliates and Sublicensees.

5.7 **Transfer of Responsibility for Manufacturing**. Upon request by Akebia (but no later than the date of delivery of the Initial Supply to Akebia or its designee, as the case may be), on a

manufacturer-by-manufacturer and material-by-material basis, the Parties shall collaborate to [***], each a "**Manufacturing Transfer Plan**"). For the avoidance of doubt, Akebia may request the [***].

5.8 **Non-Manufacturing Information Sharing**. In addition to Cyclerion's obligations set forth in Section 5.7, Cyclerion will provide to Akebia copies of all Cyclerion Know-How that is necessary or reasonably useful for Akebia to Develop, perform Medical Affairs with respect to, Commercialize, and otherwise use, sell, offer for sale, or import the Licensed Compounds or Products in the Territory in accordance with the terms and conditions of this Agreement no later than [***] after the Effective Date. Thereafter, Cyclerion will provide to Akebia copies of all Cyclerion Know-How that is made, conceived, discovered, or otherwise generated following such initial transfer of Cyclerion Know-How and is necessary or reasonably useful to continue to enable Akebia to Develop, perform Medical Affairs with respect to, Commercialize, and otherwise use, sell, offer for sale, or import any Licensed Compounds and Products in the Territory in accordance with the terms and conditions of this Agreement. In addition to providing copies of the Cyclerion Know-How in accordance with this Section 5.8, Cyclerion will, to the extent reasonably requested by Akebia, make its personnel reasonably available to Akebia for the purposes of assisting on issues arising during Akebia's Exploitation under the Cyclerion Intellectual Property of the Licensed Compounds and Products in the Territory.

Article 6
MEDICAL AFFAIRS AND COMMERCIALIZATION

6.1 **Medical Affairs and Commercialization**. Subject to the terms of this Agreement, Akebia shall have sole control over and decision-making authority with respect to the performance of Medical Affairs and Commercialization of the Products in the Field in the Territory, including the establishment and implementation of its commercial strategy. Akebia shall be solely responsible for all costs and expenses associated with its performance of Medical Affairs and Commercialization of the Products in the Field in the Territory.

6.2 **Diligence.** Akebia shall use Commercially Reasonable Efforts to [***].

6.3 **Statements and Compliance with Applicable Law.** Akebia shall, and shall cause its Affiliates to, comply with all applicable law with respect to the Commercialization of Products.

Article 7
PAYMENTS

7.1 **Upfront Payment.** No later than [***], Akebia shall pay Cyclerion an upfront amount equal to Three Million Dollars ($3,000,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.

7.2 **Development and Regulatory Milestone Payments.** In partial consideration of the rights granted by Cyclerion to Akebia hereunder and subject to the terms and conditions set forth in this Agreement, including Section 7.2, Akebia shall pay to Cyclerion the applicable milestone payment

set forth in Table 7.2 within [***] after the first achievement of each of the following milestones by Akebia or its Affiliates for the first Product:

Table 7.2 – Development and Regulatory Milestones	
U.S.	***Development and Regulatory Milestone Payment***
Initiation of a Phase 2 Clinical Trial in the U.S. for a Product for the first Indication	[***]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the first Indication	[***]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the second Indication	[***]
Receipt of Regulatory Approval by the FDA for a Product for the first Indication	[***]
Receipt of Regulatory Approval by the FDA for a Product for the second Indication	[***]
[***]	[***]
[***]	***Development and Regulatory Milestone Payment***
Receipt of [***] Regulatory Approval for a Product for the first Indication	[***]
Receipt of [***] Regulatory Approval for a Product for the second Indication	[***]
[***]	[***]
[***]	***Development and Regulatory Milestone Payment***
Receipt of Regulatory Approval by [***] for a Product for the first Indication	[***]
Receipt of Regulatory Approval by [***] for a Product for the second Indication	[***]
[***]	[***]

Each milestone payment in this Section 7.2 shall be payable one time only upon the first achievement of such milestone by the first Product.

If Akebia or its Affiliates achieves any milestone set forth in this Section 7.2 for a particular Product in a particular Indication before an earlier listed milestone for the same Product in the same Indication, then the earlier listed milestone shall become payable at the same time as the achieved milestone for the same Product in such Indication. No milestone payments in this Section 7.2 shall be due based on the achievement of any of the foregoing milestone events by any Significant Sublicensee.

7.3 **Delayed Phase 2 Milestone Payment**. If Akebia or its Affiliates have not Initiated a Phase 2 Clinical Trial in the U.S. for any Product by the date that is [***] from the Initial Supply Notice Date, then within [***] of such date Akebia shall pay Cyclerion a one-time milestone of [***], which payment shall be [***] for the Initiation of a Phase 2 Clinical Trial in the U.S. for a Product for the first Indication. If (a) Akebia has not [***].

7.4 **Sales Milestone Payments.**

(a) In partial consideration of the rights granted by Cyclerion to Akebia hereunder, subject to the terms and conditions of this Agreement, including Section 7.4(b), on [***], in the event the aggregate Net Sales of all Products recorded by Akebia, or any of its Affiliates [***] in [***] first exceeds each of the three sales milestone events set forth in Table 7.4 below, Akebia shall pay to Cyclerion the sales milestone payment in the corresponding amount set forth in the right-hand column of the table. In the event that Akebia or its Affiliates [***] that is exceeded [***]. Each such milestone payment shall be due within [***] of the end of [***] in which such milestone was achieved.

Table 7.4 – Sales Milestones	
[***]	**[***]**
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, each sales milestone payment in this Section 7.4(a) shall be payable one time only upon the first achievement of such sales milestone event [***]. For the avoidance of doubt, (i) the maximum aggregate amount payable by Akebia pursuant to this Section 7.4(a) [***], and (ii) the maximum aggregate amount payable by Akebia pursuant to this Section 7.4(a) worldwide is [***].

(b) [***].

7.5 **Royalty Payments.**

(a) **Akebia Royalty Rate – [***].** As further consideration for the rights granted to Akebia hereunder, subject to the terms and conditions of this Agreement, including the other terms of this Section 7.5, [***], during the Royalty Term for a Product [***], Akebia shall pay to Cyclerion tiered royalties based on Net Sales recorded by Akebia or its Affiliates of all Products in [***] in a [***] at the applicable royalty rates set forth below:

Table 7.5 – Akebia Royalties [***]	
[***]	**[***]**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) **Significant Sublicensee.** [***]. In addition, notwithstanding any provision to the contrary set forth in this Agreement, Akebia shall have no obligation pay Cyclerion any royalties based on sales of Products sold by any such Significant Sublicensees other than as set forth in Section 7.6.

(c) **ROW Royalty Rate.** As further consideration for the rights granted to Akebia hereunder, subject to the other terms of this Section 7.5, during the Royalty Term of a Product [***], unless Akebia has entered into an agreement with a Significant Sublicensee that includes a grant of rights [***], Akebia shall pay to Cyclerion a royalty of [***] on Net Sales recorded

by Akebia or its Affiliates or Sublicensees (other than a Significant Sublicensee) of all Products [***] in a [***].

(d) **Royalty Term.** Akebia shall have no obligation to pay any royalty pursuant to this Section 7.5 with respect to sales of any Product in any country or other jurisdiction after the Royalty Term for such Product in such country or other jurisdiction has expired.

(e) **Reductions.**

(i) **Expiration of Valid Claims**. Subject to Section 7.5(e)(iv), on a Product-by-Product and country-by-country basis, during [***] following [***], the royalty rate set forth in this Section 7.5 with respect to such country shall be reduced by [***].

(ii) **Generic Product Entry**. Subject to Section 7.5(e)(iv), in the event that (A) a Generic Product for a Product is made commercially available in any country in the Territory during the Royalty Term and (B) the Net Sales of such Product in such country [***] are [***] of the royalties otherwise due to Cyclerion with respect to such Product in such country.

(iii) **Third Party Intellectual Property**. If Akebia makes any payment under any agreement with a Third Party pursuant to which Akebia is granted a license, sublicense or other rights under a Patent or other intellectual property right owned or controlled by a Third Party [***] to Exploit one or more Products, then Akebia may offset against the royalties due to Cyclerion for such Product(s) an amount equal to [***] of the amounts paid in consideration for, or in connection with obtaining, such rights from such Third Party (including any upfront payments, milestone payments, royalties, litigation costs, settlement fees, or other expenses relating to the foregoing) in all cases, subject to Section 7.5(e)(iv).

(iv) **Maximum Payment Adjustments**. [***], in no event will the adjustments under Section 7.5(e)(i), Section 7.5(e)(ii), and Section 7.5(e)(iii) taken together reduce the royalties due to Cyclerion in a country [***] with respect to a Product by more than [***] of the amount that would have been due [***] for such Product in such country but for the application of the reductions in this Section 7.5(e) (the "**Reduction Floor**"); *provided* that [***].

(f) **Royalty Payments and Reports.** Akebia shall calculate all amounts payable to Cyclerion pursuant to this Section 7.5 at the end of each Calendar Quarter, which amounts shall be converted to Dollars in accordance with Section 7.8. Within [***] after the end of each Calendar Quarter after the First Commercial Sale of a Product in the Territory, Akebia shall provide to Cyclerion a written, good faith estimate of the amount of Net Sales of each Product made by Akebia and its Affiliates in each country or other jurisdiction in the Territory during the applicable Calendar Quarter for which royalties pursuant to this Section 7.5 are payable. Akebia shall pay to Cyclerion the royalty amounts due with respect to a given Calendar Quarter within (i) [***] after the end of such Calendar Quarter or (ii) for the portion of any such payment is due to sales by a Sublicensee, as soon as practicable after Akebia is paid by such Sublicensee. Each payment of royalties due to Cyclerion shall be accompanied by a statement of the amount of Net Sales of each Product made by Akebia and its Affiliates and its Sublicensees (other than Significant Sublicensees) in each country or other jurisdiction in the Territory during the applicable Calendar Quarter for which

royalties pursuant to this Section 7.5 are payable (including such amounts expressed in local currency and as converted to Dollars), and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter.

7.6 **Sublicense Income.**

(a) Akebia shall pay to Cyclerion an amount equal to [***].

(b) Akebia shall pay to Cyclerion an amount equal to [***].

(c) For purposes of calculating [***].

(d) Akebia shall pay Cyclerion its portion of all [***].

7.7 **Payment Method**. All payments due under this Agreement to Cyclerion shall be made by bank wire transfer in immediately available funds to an account as designated by Cyclerion from time to time by notice to Akebia. All payments hereunder shall be made in Dollars.

7.8 **Exchange Rate**. The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed under this Agreement shall be equal to the exchange rate between each currency of origin and Dollars as reported by Citibank, N.A., or an equivalent resource as agreed by the Parties, on the last Business Day of the Calendar Quarter in which the applicable Net Sales were made.

7.9 **Taxes**.

(a) [***].

(b) [***].

7.10 **Interest**. If Akebia fails to make any payment due to Cyclerion under this Agreement, then interest shall accrue on a daily basis at the annual rate equal to [***] above the then-applicable prime commercial lending rate of Citibank, N.A., New York, New York, or at the maximum rate permitted by applicable law, whichever is the lower.

7.11 **Financial Records; Audit.**

(a) **Retention.** Akebia shall, and shall cause its Affiliates and Sublicensees to, keep for at least [***] following the end of the Calendar Year to which they pertain accurate records of the Net Sales of the Products in the Territory, the number of Product units sold, and other matters relating to the calculation of Net Sales and the royalties paid to Cyclerion hereunder, and matters relating to Non-Commercial Sublicense Income and Commercial Sublicense Income paid to Cyclerion hereunder, in sufficient detail to calculate relevant amounts payable hereunder and to verify compliance with its obligations under this agreement.

(b) **Access to Records.** At the request of Cyclerion, Akebia shall, and shall cause its Affiliates and Sublicensees to, permit an independent auditor designated by Cyclerion and reasonably acceptable to Akebia, at reasonable times and upon at least [***] advance notice, to audit the books and records maintained pursuant to Section 7.11(a) to ensure the accuracy of all reports and payments made hereunder relating to Net Sales, royalties, Non-Commercial

Sublicense Income, and Commercial Sublicense Income. Except as provided below, the cost of this audit shall be borne by Cyclerion, unless the audit reveals a variance of more than [***] from the reported amounts, in which case Akebia shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by Akebia, then Akebia shall pay the additional amounts, with interest from the date originally due as provided in Section 7.10, or (ii) excess payments were made by Akebia, then Cyclerion shall reimburse such excess payments, in either case ((i) or (ii)), within [***] after the date on which such audit is completed by Cyclerion.

Article 8
LICENSE RIGHTS AND LIMITATIONS

8.1 **Licenses to Akebia.** Subject to the terms and conditions of this Agreement, including 8.2 and Cyclerion's retained rights under Section 8.7, Cyclerion hereby grants and will grant to Akebia and its Affiliates an exclusive royalty-bearing, worldwide license (with the right to sublicense solely in accordance with Section 8.4) under the Cyclerion Intellectual Property, solely to Exploit the Licensed Compounds and the Products in the Field in the Territory, which license shall include the exclusive right to Develop, Manufacture, make, use or import [***] and all other intermediates and other precursors to the Licensed Compounds and the Products solely for the purpose of Manufacturing the Licensed Compounds and the Products in the Field in the Territory in accordance with this Agreement.

8.2 **Certain Restrictions**. Akebia shall not, and shall cause its Affiliates not to (a) directly or indirectly Exploit any Licensed Compound or Product, or any intermediate or other precursor thereof, in any Excluded Indication in any country or other jurisdiction in the Territory, or (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly Exploit any Licensed Compound or Product, or any intermediate or other precursor thereof, in any [***].

8.3 **Assigned Trademarks.** Cyclerion hereby assigns to Akebia all of its rights, title, and interests in and to the Assigned Trademarks, and agrees to take all actions reasonably requested by Akebia, at Akebia's expense, to evidence such assignment. Akebia hereby accepts such assignment.

8.4 **Rights to Sublicense**. Akebia shall have the right to grant to any Third Party or Affiliate sublicenses of the rights granted with respect to the Products or Cyclerion Intellectual Property under Section 8.1 [***] without the prior written consent of Cyclerion, *provided* that each sublicense agreement with a Third Party must (a) be consistent with and expressly made subject to the applicable terms and conditions of this Agreement, (b) contain terms obligating any Third Party to whom a sublicense is granted to comply with the intellectual property provisions of this Agreement, and (c) contain obligations of confidentiality and non-use no less stringent that the confidentiality terms of this Agreement. Akebia shall remain primarily liable to Cyclerion for the performance of all its obligations under, and Akebia's compliance with all the provisions of, this Agreement, and shall be responsible and liable for any conduct by any of its Sublicensees that would amount to a breach of the terms of this Agreement if performed by Akebia, in each case to the same extent as if Akebia itself has committed any such breach. [***] after execution of any sublicense of the rights granted to Akebia hereunder to a Sublicensee, Akebia will provide Cyclerion with a true and complete copy of any executed sublicense agreement with any Sublicensee, subject to Akebia's right to redact any confidential information contained therein that is not necessary for Cyclerion to determine compliance with the terms of this Agreement.

8.5 **Survival of Sublicenses**. Upon [***] not then in breach of its sublicense agreement or the terms of this Agreement applicable to such Sublicensee, Cyclerion will enter into a direct license from

Cyclerion to such Sublicensee on the same terms as this Agreement, taking into account any difference in license scope, territory, and duration of sublicense grant (each a "**New License Agreement**"); *provided*, *however*, that, [***]. Under any such New License Agreement between Cyclerion and such former Sublicensee, such Sublicensee will be required to pay to Cyclerion the same amounts in consideration for such direct grant as Cyclerion would have otherwise received from Akebia pursuant to this Agreement on account of such Sublicensee's Exploitation of the Products had this Agreement not been terminated. Under such New License Agreement, the Parties agree that Cyclerion will not be bound by any grant of rights broader than, and will not be required to perform any obligation other than those rights and obligations contained in, this Agreement and all applicable rights of Cyclerion set forth in this Agreement will be included in such New License Agreement.

8.6 **No Implied Licenses.** Neither Party grants (or agrees to grant) to the other Party any right or license to use any of its intellectual property, Know-How, or other proprietary information, materials or technology, or to practice any of its Patents, except as expressly set forth in this Agreement, or any of its Trademarks (other than the Assigned Trademarks).

8.7 **Retained Rights**. Notwithstanding any provision to the contrary set forth in this Agreement, Cyclerion (on behalf of itself and its licensees, other than Akebia and its Sublicensees) expressly retains the right under the Cyclerion Intellectual Property to (a) exercise its rights and perform its obligations under this Agreement, (b) Manufacture the Licensed Compounds and Products (including the right to Develop, Manufacture, make, use or import [***] and all other intermediates and precursors to the Licensed Compounds and the Products for the purposes of Manufacturing Licensed Compound and Products) solely for the purpose of supplying the same to Akebia or its Affiliates in accordance with this Agreement, and (c) Exploit [***] and all other intermediates and precursors to the Licensed Compounds and the Products for the purpose of Exploiting compounds and products that are not Licensed Compounds or Products. Any rights not expressly granted to Akebia by Cyclerion under this Agreement are hereby retained by Cyclerion.

8.8 **Non-Competition**.

(a) **Cyclerion Obligations**. Cyclerion shall not, and shall cause its Affiliates not [***].

(b) **Cyclerion Indications**. Notwithstanding Section 8.8(a), [***].

(c) **Acquisition of Restricted Product.** Notwithstanding Section 8.8(a), [***].

Article 9
INTELLECTUAL PROPERTY

9.1 **Ownership of Intellectual Property.**

(a) **Ownership of Technology**. As between the Parties, each Party shall own and retain all rights, title, and interests in and to any and all: (i) inventions and other Know-How conceived, discovered, developed, or otherwise made by or on behalf of such Party (or its Affiliates or Sublicensees) under or in connection with this Agreement, whether or not patented or patentable, and any and all Patents Covering any such Know-How, and (ii) other inventions and other Know-How, Patents, and other intellectual property rights that are owned or otherwise Controlled (other than pursuant to the license grants set forth herein) by such Party, its Affiliates, or its licensees or Sublicensees.

(b) **Ownership of Joint Patent and Joint Know-How.** As between the Parties, the Parties shall each own an equal, undivided interest in any and all (i) inventions and other Know-How that are conceived, discovered, developed, or otherwise made jointly by or on behalf of Cyclerion or its Affiliates, on the one hand, and Akebia or its Affiliates or Sublicensees, on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable (the "**Joint Know-How**"), and (ii) Patents (the "**Joint Patents**") and other intellectual property rights with respect to the inventions and other Know-How described in clause (i) (together with Joint Know-How and Joint Patents, the "**Joint Intellectual Property Rights**"). Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, (and in the case of Akebia, its Sublicensees) to so disclose, the development, making, conception, or reduction to practice of any Joint Know-How or Joint Patents. Subject to the licenses and rights of reference granted herein and each Party's respective exclusivity obligations hereunder, each Party shall have the right to exploit the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

(c) **Manufacturing Process Improvements.**

(i) **Unblocking Manufacturing Process Patent License**. Akebia hereby grants Cyclerion a [***], under any Manufacturing Process Patents for any and all purposes, other than to Develop or Commercialize a Product in the Field in the Territory.

(ii) **Right to Negotiate for a License to Manufacturing Process Improvements**. Upon Cyclerion's [***], the Parties will discuss in good faith the terms on which Akebia would grant to Cyclerion a [***] to any Manufacturing Process Improvements.

All Manufacturing Process Improvements shall be the Confidential Information of Akebia and Akebia shall be under no obligation to disclose the technical details or other information required to enable Cyclerion to practice any Manufacturing Process Improvements, except pursuant to the terms of a license agreement negotiated between the Parties as provided herein. [***].

(d) **United States Law.** The determination of whether Know-How and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright, or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable law in the U.S., irrespective of where such conception, discovery, development or making occurs.

9.2 **Patent Prosecution and Maintenance**.

(a) **Prosecution of Control Transferring Patents Before Patent Transfer Date.**

(i) As between the Parties, from the Effective Date until the Patent Transfer Date, unless otherwise agreed by the Parties, Cyclerion shall control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of those Cyclerion Patents, other than the Non-Control Transferring Patent, including those Cyclerion Patents set forth on

Schedule 9.2(a) (the "**Control Transferring Patents**"), at its sole cost and expense and by Cyclerion's counsel as of the Effective Date, *provided* that:

(1) If Cyclerion chooses to use counsel other than its counsel as of the Effective Date, then such counsel shall be reasonably acceptable to Akebia;

(2) Cyclerion shall consult with Akebia on all prosecution strategies, including what subject matter to pursue in an application, strategies for responding to substantive communications from a patent office, and divisional filing strategies with respect to the Control Transferring Patents;

(3) Cyclerion shall provide Akebia copies of all correspondence received from the relevant patent office regarding the Control Transferring Patents;

(4) Cyclerion shall provide Akebia copies of all documents relevant to such filing and prosecution at least [***] prior to submission of such documents to the applicable patent office;

(5) Cyclerion shall incorporate all reasonable comments with respect to any Control Transferring Patent provided by Akebia no later than [***] prior to the next deadline for the applicable action that must be taken with respect to such Control Transferring Patent, except that the foregoing obligation will not be construed to require Cyclerion to take any course of action that would negatively impact patent protection for Cyclerion's proprietary compound, olinciguat, unless such course of action may be necessary to maintain patent protection for praliciguat;

(6) Cyclerion shall not, without the prior written consent of Akebia, file a divisional application for any Control Transferring Patent; provided, however, that, no such consent shall be required to file any divisional application that contains claims solely Covering Cyclerion's proprietary compound, olinciguat, unless such divisional filing could negatively impact any issued patent or pending application Covering praliciguat, in which case, prior written consent of Akebia is required;

(7) Cyclerion shall not, without the prior written consent of Akebia, abandon or cease prosecution or maintenance of any Control Transferring Patent;

(8) Cyclerion shall use reasonable efforts to prepare, file, prosecute, and maintain the Control Transferring Patents so as to maximize the protection offered by such Control Transferring Patents for the Licensed Compounds and Products;

(9) the Control Transferring Patents shall be deemed the Confidential Information of both Parties;

(10) Cyclerion shall not, without the prior written consent of Akebia, (A) grant any Third Party control over the preparation, filing, prosecution, or maintenance of any Control Transferring Patent or (B) any right to comment on Cyclerion's preparation, filing, prosecution, or maintenance of any Control Transferring Patent that either (I) would permit such Third Party to provide comments directly to Akebia after the Patent Transfer Date, or (II) exceeds or is otherwise incompatible with Cyclerion's right to provide comments after the Patent Transfer Date as provided under Section 9.2(b)(i); and

(11) Cyclerion shall not, without the prior written consent of Akebia, take or fail to take any action (whether alone or in conjunction with other actions) in the course of

preparation, filing, prosecution, and maintenance of any Control Transferring Patent that could materially diminish or limit the scope of such Control Transferring Patent's protection of one or more Licensed Compounds or Products (if such Control Transferring Patent were to issue in its then-current form) in favor of increasing the protection of any other compound or product, including for the avoidance of doubt, Cyclerion's proprietary compound, olinciguat. If at any time any course of action taken by Cyclerion may negatively impact patent protection for the Licensed Compounds or Products, then upon Akebia's request Cyclerion shall cease such action.

(b) **Prosecution of Control Transferring Patents After Patent Transfer Date and Joint Patents**.

(i) As between the Parties, Akebia shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of (A) after the Patent Transfer Date, the Control Transferring Patents and (B) after the Effective Date, Joint Patents (collectively, ((A) and (B)), the "**Akebia Primary Patents**"), in each case, at its sole cost and expense and by counsel of its own choice that is reasonably acceptable to Cyclerion. Akebia shall (x) keep Cyclerion reasonably informed of all substantive matters relating to prosecution and maintenance of those Akebia Primary Patents that Cover Cyclerion's proprietary compound, olinciguat, including by providing Cyclerion copies of all documents relevant to such filing and prosecution at least [***] prior to submission of such documents to the applicable patent office with respect to any such Akebia Primary Patents for Cyclerion's review and comment and by providing Cyclerion reasonable advance written notice of [***].

(ii) In the event that Akebia desires to abandon or cease prosecution or maintenance of any Akebia Primary Patent, Akebia shall provide reasonable prior written notice to Cyclerion of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Akebia Primary Patent in the relevant patent office). In such case, upon Cyclerion's written election provided no later than [***] after such notice from Akebia, Cyclerion shall have the right to assume the prosecution and maintenance of such Akebia Primary Patent at Cyclerion's expense.

(c) **Prosecution of Non-Control Transferring Patent**.

(i) As between the Parties, Cyclerion shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings, and defense of validity or enforceability challenges, in each case, except as provided in Section 9.4(c)) of the Cyclerion Patents set forth on Schedule 9.2(c) (the "**Non-Control Transferring Patent**"), at its sole cost and expense and by counsel of its own choice. Cyclerion will keep Akebia reasonably informed of all substantive matters relating to prosecution and maintenance of the Non-Control Transferring Patent, including by providing Akebia copies of all documents relevant to such filing and prosecution at least [***] prior to submission of such documents to the applicable patent office with respect to any such Non-Control Transferring Patent for Akebia's review and comment and will incorporate any

reasonable comments with respect thereto provided by Akebia no later than [***] prior to the next deadline for the applicable action that must be taken with respect to any such Non-Control Transferring Patent. Cyclerion shall not take any action that could jeopardize the validity or enforceability of the Akebia Primary Patents or any action may negatively impact the Akebia Primary Patents.

(ii) In the event that Cyclerion desires to abandon or cease prosecution or maintenance of any Non-Control Transferring Patent, Cyclerion shall provide reasonable prior written notice to Akebia of such intention to abandon (which notice shall, to the extent possible, be given no later than [***] prior to the next deadline for any action that must be taken with respect to any such Non-Control Transferring Patent in the relevant patent office). In such case, upon Akebia's written election provided no later than [***] after such notice from Cyclerion, Akebia shall have the right to assume the prosecution and maintenance of such Non-Control Transferring Patent at Akebia's expense. If Akebia does not provide such election within [***] after such notice from Cyclerion, Cyclerion may, in its sole discretion, continue or discontinue prosecution and maintenance of such Non-Control Transferring Patent.

(d) **Update to Schedule 1.30 upon Patent Transfer.** [***] after the Patent Transfer Date, but in any event within [***], Cyclerion shall provide Akebia an updated Schedule 1.30 setting forth all Cyclerion Patents existing as of the Patent Transfer Date.

(e) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided above in this Section 9.2, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

(f) **Patent Term Extensions and Patent Linkage.** Akebia will have the sole right and discretion to determine and control (i) all filings of requests for patent term extensions, supplementary protection certificates, or equivalents thereto in any country in the Territory with respect to the Akebia Primary Patents (each a "**Patent Term Extension**") and (ii) linking of Patents to an approved Product such as in the FDA's "Orange Book" or its foreign equivalent in any country in the Territory with respect to Cyclerion Patents (each "**Patent Linkage**"). [***]. Upon the request of Akebia [***], Cyclerion will provide support, assistance, and all necessary documents, in full executed form if needed, to Akebia for the purpose of supporting, filing, obtaining, and maintaining Patent Term Extensions and Patent Linkage.

9.3 **Patent Contacts**. Each Party will designate patent counsel representatives who will be responsible for coordinating the activities between the Parties in accordance with this Article 9 (each a "**Patent Contact**"). Each Party will designate its initial Patent Contact within [***] following the Effective Date and will promptly thereafter notify the other Party of such designation. Each Party will promptly notify the other Party of any substitution of another person as its Patent Contact. The Patent Contacts will, from time to time, discuss the respective Patent strategies of the Parties relating to this Agreement. In particular the Patent Contacts will discuss the global intellectual property activities under this Agreement and review and update the list of Cyclerion Patents from time to time. The Patent Contacts will meet at least [***], or as otherwise agreed to by the Parties until the Patent Transfer Date, and thereafter at least annually.

9.4 **Infringement by Third Parties.**

(a) **Notice**. Each of Akebia and Cyclerion shall promptly notify the other Party in writing of any alleged or threatened infringement of any Non-Control Transferring Patent or Akebia Primary Patent by a Third Party in the Territory of which the Party becomes aware (including alleged or threatened infringement based on the Exploitation of a product that could be competitive with a Product in the Territory (a "**Product Infringement**")).

(b) **Right to Bring Suit**. [***] shall have the first right to bring and control any action or proceeding with respect to any alleged or threatened infringement of a Cyclerion Patent or Joint Patents in the Territory. If [***] does not bring and continue pursuing diligently an action or proceeding against, or otherwise cause the cessation of, a Product Infringement of any Cyclerion Patent or Joint Patent by or after (A) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such an action, whichever comes first, then [***] shall have the right to bring and control an infringement action under the applicable Cyclerion Patents or Joint Patents with respect to such Product Infringement at its own expense and by counsel of its own choice.

(c) **Defense of Patents in Related Proceedings**. Notwithstanding Section 9.2(c), as between the Parties, [***] shall have the first right, but not the obligation, to control the defense (including any interferences, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of Non-Control Transferring Patent if such defense is related to any actual or threatened enforcement of such Patents by [***] under this Section 9.4, at [***] sole cost and expense and by counsel of its own choice; *provided* that [***] shall obtain the written consent of [***] prior to settling or compromising such defense, such consent not to be unreasonably withheld, conditioned or delayed. [***] may participate in any such claim, suit, or proceeding in the Territory with counsel of its choice at its own expense. If [***] elects not to defend or control the defense of any such Non-Control Transferring Patent in a suit brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then [***] may conduct and control the defense of any such claim, suit, or proceeding at its own expense. As between the Parties Akebia shall have the first right, but not the obligation, to control the defense (including any interferences, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of Akebia Primary Patents if such defense is related to any actual or threatened enforcement of such Patents by Akebia under this Section 9.4 and any settlement or compromise of such defense related to the Akebia Primary Patents shall be in Akebia's sole discretion.

(d) **Cooperation; Settlement**. For any action or proceeding brought by a Party under this Section 9.4 (the "**Initiating Party**"), regardless of which Party brings such action or proceeding, the other Party (the "**Non-Initiating Party**") hereby agrees to cooperate reasonably in any such effort, all at the Initiating Party's expense, and the Parties shall reasonably cooperate to address new facts or circumstances that come to light during the course of any such action or proceeding that may affect the need for one Party or the other to participate in such action. The Non-Initiating Party agrees to be joined as a party plaintiff, at the Initiating Party's expense, in any such action if needed for the Initiating Party to bring or continue an infringement action hereunder. Cyclerion shall, at its own expense and with its own counsel, have the right to participate in any action brought by Akebia under this Section 9.4. Akebia shall, at its own expense and with its own counsel, have the right to participate in any action brought by Cyclerion involving a Product Infringement. Neither Party may settle any action or proceeding brought under this Section

9.4 in a manner that, or knowingly take any other action in the course thereof that, materially adversely affects the other Party's interest in the Non-Control Transferring Patent or Akebia Primary Patents, without the written consent of such other Party, such consent not to be unreasonably withheld, conditioned or delayed.

(e) **Recoveries**. Any recovery realized as a result of such litigation described in Section 9.4 (whether by way of settlement or otherwise) shall be first, allocated to [***]. Any remainder after [***] shall be [***]; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales with respect to a Product, then such award or settlement will be treated [***].

9.5 **Third Party Claims for Infringement or Misappropriation.** If the Exploitation of a Licensed Compound or Product in the Territory under this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by Akebia (or its Affiliates or Sublicensees), then the Party with knowledge of such actual or potential claim shall [***] notify the other Party thereof in writing. [***] shall have the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice. [***] may participate in any such claim, suit, or proceeding with counsel of its choice at its own expense. If [***] elects (in a written communication submitted to [***] within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such claim, suit, or proceeding, within such time periods so that [***] is not prejudiced by any delays, [***] may conduct and control the defense of any such claim, suit, or proceeding at its own expense. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding. Any recoveries by [***] of any sanctions awarded to [***] and against a party asserting a claim being defended under this Section 9.5 shall be applied first to reimburse [***] and [***] for its reasonable out-of-pocket costs of defending such claim, suit, or proceedings. The balance of any such recoveries shall be retained by [***], provided, however, [***].

9.6 **Product Trademarks**. Akebia will have the right to brand the Products using Trademarks it determines appropriate for the Product, which may vary by region or within a region (the "**Product Marks**"). Akebia will own all rights in the Product Marks in the Territory and will register and maintain the Product Marks in the Territory that it determines reasonably necessary, at its expense. Akebia will be solely responsible, at its expense, for enforcing such Product Marks against any Third Party infringement as Akebia reasonably determines in its sole discretion.

Article 10
CONFIDENTIALITY

10.1 **Confidentiality Obligations**. At all times during the Term and for a period of [***] following termination or expiration hereof, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use for any purpose any Confidential Information furnished or otherwise made known to it by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary for the performance of, or the exercise of such Party's rights under, this Agreement. The terms of this Agreement shall be the Confidential Information of both Parties, and each Party shall be deemed to be the receiving Party thereto. To the extent the receiving Party can demonstrate by documentation or other competent proof, the following information will not be deemed Confidential Information and the confidentiality and non-use obligations under this Section 10.1 will not apply to any such information that:

(a) has been published by a Third Party or is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no wrongful act, fault, or negligence on the part of the receiving Party;

(b) has been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

(c) is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

(d) has been independently developed by or for the receiving Party without reference to, or use or disclosure of the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

10.2 **Permitted Disclosures.** Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) required to be disclosed pursuant to law, regulation, applicable stock exchange rule or made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial, and local governmental or regulatory body of competent jurisdiction, including under subpoena, document requests related to litigation, or by reason of filing with securities regulators (including, for the avoidance of doubt, filing this Agreement as a material agreement as may be required pursuant to securities regulations); *provided*, *however*, that the receiving Party shall first have given prompt written notice (and to the extent practicable, at least [***] notice) to the disclosing Party and provides reasonable assistance to the disclosing Party in taking whatever action the disclosing Party deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Section 10.2(a), the receiving Party shall furnish only that portion of Confidential Information that the receiving Party is required to disclose. Notwithstanding the foregoing, at [***] prior to either Party filing this Agreement with securities regulators, such filing Party will furnish a proposed redacted copy of this Agreement to the other Party for review, and such filing Party will incorporate all reasonable additional redactions requested by the other Party;

(b) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any Regulatory Submission or in connection with any inspection or audit by any Regulatory Authority;

(c) made by the receiving Party or its Affiliates or sublicensees to its or their actual or *bona fide* potential advisors, consultants, clinicians, vendors, service providers, contractors, licensees, collaborators, or sublicensees (and to each of their respective bankers, lawyers, accountants, or agents) as may be [***] in connection with the Exploitation of the Licensed

Compounds or the Products, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement; *provided*, *however*, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 10;

(d) subject to Section 9.4, made by or on behalf of the receiving Party to a patent authority as may be reasonably [***] for purposes of filing, prosecuting, maintaining, enforcing, or defending a Patent as permitted under this Agreement; or

(e) made by or on behalf of the receiving Party to actual or *bona fide* potential investors or acquirers or other Third Party transactional parties (and to each of their respective bankers, lawyers, accountants, or agents), as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided*, *however*, that such Third Parties shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to Section 10.1 (with durations of confidentiality and non-use as appropriate).

10.3 **Use of Name.** Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity, without the prior written approval of such other Party in each instance, except for either Party's references to the other as the licensor or licensee (as applicable) or a collaboration partner under this Agreement. The restrictions imposed by this Section 10.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by applicable law; *provided* that such Party shall use reasonable efforts to submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

10.4 **Public Announcements.** The Parties will cooperate in good faith and agree upon the content of a press release, which may be issued by Cyclerion following the Effective Date. Except as set forth in Section 10.2, neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent. Without limiting the foregoing, to the extent permitted by applicable law and any applicable stock exchange rules, [***]. After the permitted public disclosure by a Party, either Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein.

10.5 **Residual Knowledge**. Notwithstanding any provision to the contrary set forth in this Agreement, Confidential Information will not include any knowledge, technique, experience, or Know-How that is retained in the unaided memory of any authorized representative of the receiving Party after having access to such Confidential Information ("**Residual Knowledge**"). Any use made by the receiving Party of any such Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

10.6 **Return of Confidential Information.** Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with

respect to Confidential Information to which such first Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, however, the other Party shall be permitted to retain copies of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

Article 11
REPRESENTATIONS AND WARRANTIES

11.1 **Representations and Warranties by Cyclerion.** Cyclerion hereby represents and warrants to Akebia as of the Effective Date as follows:

(a) the execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate actions;

(b) this Agreement constitutes a valid obligation of Cyclerion and is binding and enforceable against Cyclerion in accordance with the terms hereof;

(c) Cyclerion and, to Cyclerion's Knowledge, its contractors and consultants, have complied in all material respects with all applicable law in the Development and Manufacture of the Licensed Compound and Product prior to the Effective Date;

(d) Cyclerion has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and there is no contractual restriction or other legal obligation binding on Cyclerion that would be contravened by execution and delivery of this Agreement or by the performance or observance of its terms;

(e) Cyclerion has not granted, and will not grant during the Term, a license or sublicense to any Affiliate or Third Party under the Cyclerion Intellectual Property that would conflict with the rights granted to Akebia hereunder;

(f) all Cyclerion Patents existing as of the Effective Date are set forth on Schedule 1.30, and such Cyclerion Patents represent all Patents Cyclerion Controls that are necessary or reasonably useful for Akebia's Exploitation of the Licensed Compounds or the Products as contemplated by this Agreement;

(g) Cyclerion is the sole and exclusive owner of the entire right, title, and interest in the Cyclerion Patents set forth on Schedule 1.30, free of any encumbrance, lien, or claim of ownership by any Third Party;

(h) (i) there are no claims, judgments or settlements against Cyclerion pending or, to Cyclerion's Knowledge, threatened, that invalidate or seek to invalidate the Cyclerion Patents set forth on Schedule 1.30, (ii) there is no opposition pending in any jurisdiction outside of the United States that challenges the validity or enforceability of, or Cyclerion's

ownership rights in, any of the Cyclerion Patents set forth on Schedule 1.30 in that jurisdiction, (iii) there is no litigation pending against Cyclerion or any Affiliate of Cyclerion that alleges that any of the activities contemplated by this Agreement will violate any Patent or other intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation), and (iv) Cyclerion has not received any written correspondence from a Third Party alerting Cyclerion of any intellectual property rights that allegedly would be infringed by Akebia's Exploitation of a Licensed Compound or Product or asserting that any claim in the Cyclerion Patents set forth on Schedule 1.30 is invalid or unenforceable;

(i) to Cyclerion's Knowledge, the Cyclerion Patents set forth on Schedule 1.30 have been diligently prosecuted with the respective patent offices where such Cyclerion Patents have been filed in the Territory in accordance with applicable law, and all applicable fees necessary to maintain the Cyclerion Patents set forth on Schedule 1.30 have been paid on or before the due date for such payment;

(j) each individual who is an inventor of or otherwise has or has had any rights in or to any Cyclerion Patents identified as being owned by Cyclerion on Schedule 1.30 has assigned to Cyclerion all of his or her interest therein;

(k) Cyclerion is entitled to grant the licenses specified herein;

(l) the conception, development, and reduction to practice of any of the Cyclerion Intellectual Property have not constituted or involved the misappropriation of trade secrets or other intellectual property rights of any Third Party;

(m) the process used by Cyclerion to Manufacture the Licensed Compounds or Products (as applicable) as of the Effective Date does not require the use of any Third Party intellectual property right;

(n) to Cyclerion's Knowledge, the practice by Cyclerion or Akebia under the Cyclerion Intellectual Property or the Exploitation by Cyclerion or Akebia (or their respective Affiliates or Sublicensees) of any Licensed Compound or Product, in each case, as contemplated under this Agreement, does not and will not infringe, misappropriate, or otherwise violate any intellectual property rights of any Third Party;

(o) no Third Party has challenged the ownership, scope, duration, validity, enforceability, priority, or right to use any Cyclerion Patent (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity, or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court);

(p) Cyclerion has not previously assigned, transferred, conveyed, or granted any license or other rights under the Cyclerion Intellectual Property, except in each case where such assignment, transfer, conveyance, or grant is not inconsistent with the rights and licenses granted to Akebia under this Agreement;

(q) all rights in all inventions and discoveries made, developed or conceived by any employee or independent contractor of Cyclerion during the course of their employment (or other retention) by Cyclerion and included in the Cyclerion Know-How or that are the subject to one (1) or more Cyclerion Patents have been (or to the extent present assignment of future

inventions is not permitted by applicable law, will be) assigned in writing to Cyclerion pursuant to a written agreement to assign such inventions and discoveries to Cyclerion;

(r) the Cyclerion Know-How that constitutes trade secrets under applicable law has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality. To Cyclerion's Knowledge, no breach of such confidentiality has been committed by any Third Party;

(s) the inventions Covered by the Cyclerion Patents on Schedule 1.30 were not created pursuant to, subject to, or otherwise made in connection with any research activities funded, in whole or part, by the federal government of the United States or any agency thereof or any other governmental authority worldwide, and are not subject to the requirements of the Bayh-Dole Act or any similar provision of any applicable law;

(t) all INDs owned or Controlled by Cyclerion that cover any Licensed Compound are listed on Schedule 4.1;

(u) Cyclerion has provided to Akebia true, complete, and correct (redacted) copies of all agreements between Cyclerion or an Affiliate of Cyclerion and a Third Party relating to the Manufacture or supply of the Licensed Compounds and Products and components thereof (as applicable) that are in effect as of the Effective Date, a complete list of which are listed on Schedule 11.1(u); there are no [***] between Cyclerion or its Affiliates, on the one hand, and any Third Party relating to the Manufacture or supply of the Licensed Compounds or Products and components thereof (as applicable) to Cyclerion, on the other hand, that would limit Akebia's ability to Manufacture, or have the Licensed Compounds or Products and components thereof (as applicable) Manufactured;

(v) Cyclerion has obtained the right (including under any Patent and other intellectual property right) to use all materials (including any formulations and Manufacturing processes and procedures) [***] for the Exploitation of the Licensed Compounds or the Products, as contemplated by this Agreement, in each case that was developed or delivered by any Third Party under any agreements between Cyclerion and any such Third Party with respect to the Licensed Compounds or Products, and Cyclerion has the rights under each such agreement to transfer such materials to Akebia and its designees and to grant Akebia the right to use such materials in the Exploitation of the Licensed Compounds and Products without restriction and without payments required by Akebia beyond those set forth in this Agreement;

(w) there are no amounts that will be required to be paid by Akebia to any Third Party as a result of the Exploitation of the Licensed Compounds or Products (as applicable) that arise out of any agreements to which Cyclerion or its Affiliates are a party;

(x) all works of authorship and all other materials subject to copyright protection included in Cyclerion Know-How are original and were either created by employees of Cyclerion or its Affiliates within the scope of their employment or are otherwise works made for hire, or all right, title, and interest in and to such materials have been legally and fully assigned and transferred to Cyclerion or such Affiliate, and all rights in all Know-How and discoveries developed or invented by any employee or independent contractor of Cyclerion or such Affiliate during the course of their employment (or other retention) by Cyclerion or such Affiliate, and included in Cyclerion Know-How, or that are the subject of one or more Cyclerion Patents, have been assigned in writing to Cyclerion or its Affiliate;

(y) to Cyclerion's Knowledge: (i) there are no scientific or technical facts or circumstances that have not been disclosed to Akebia, and that would [***] the scientific, therapeutic, or commercial potential of the Products; (ii) there is nothing within Cyclerion's control that has not been disclosed to Akebia and that could [***] the acceptance, or the subsequent approval, by any Regulatory Authority of any Regulatory Submissions with respect to any Product; and (iii) except as disclosed to Akebia in Cyclerion's virtual data room, there are no [***]; and

(z) Cyclerion has provided Akebia with the opportunity to review all written material data in Cyclerion's possession relating to the subject matter of this Agreement, and has not intentionally concealed from Akebia any such material data.

11.2 **Representations and Warranties by Akebia.** Akebia hereby represents and warrants to Cyclerion as of the Effective Date as follows:

(a) The execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate actions;

(b) This Agreement constitutes a valid obligation of Akebia and is binding and enforceable against Akebia in accordance with the terms hereof; and

(c) Akebia has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and there is no contractual restriction or obligation binding on Akebia that would be contravened by execution and delivery of this Agreement or by the performance or observance of its terms.

11.3 **Debarment.** Neither Party has ever been, is not currently, nor is it the subject of a proceeding that could lead to it becoming a Debarred Entity, Excluded Entity, or Convicted Entity and it will not use in any capacity, in connection with the obligations to be performed under this Agreement, any person who is a Debarred Individual, Excluded Individual or a Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List for clinical investigators. Each Party further covenants that if, during the Term, it becomes a Debarred Entity, Excluded Entity, or Convicted Entity or if any employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual, or a Convicted Individual, or added to FDA's Disqualified/Restricted List for clinical investigators, then such Party shall immediately notify the other Party. For purposes of this provision, the following definitions shall apply:

(a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

(b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(c) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended

or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(e) "**FDA's Disqualified/Restricted List**" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor.

11.4 **Disclaimer**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

Article 12
INDEMNIFICATION

12.1 **Indemnification by Akebia**. Akebia shall indemnify Cyclerion, its Affiliates, and its and their respective directors, officers, employees, and agents ("**Akebia Indemnitees**"), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") incurred by or rendered against the Akebia Indemnitees arising from or relating to: (a) the breach by Akebia of this Agreement, (b) the gross negligence, reckless conduct, or willful misconduct on the part of Akebia or its Affiliates or Sublicensees in performing its or their obligations under this Agreement, or (c) the Exploitation by Akebia or any of its Affiliates or Sublicensees of any Licensed Compound or Product in the Territory, except, in each case ((a) – (c)), for those Losses for which Cyclerion, in whole or in part, has an obligation to indemnify Akebia pursuant to Section 12.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

12.2 **Indemnification by Cyclerion**. Cyclerion shall indemnify Akebia, its Affiliates, and its and their respective directors, officers, employees, and agents (the "**Cyclerion Indemnitees**"), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred by or rendered against the Cyclerion Indemnitees arising from or relating to: (a) the breach by Cyclerion of this Agreement, (b) the gross negligence, reckless conduct or willful misconduct on the part of Cyclerion or its Affiliates in performing its obligations under this Agreement, or (c) the Exploitation by Cyclerion or any of its Affiliates, licensees (other than Akebia), or Sublicensees of any Licensed Compound or Product in the Territory, except, in each case ((a) – (c)), for those Losses for which Akebia, in whole or in part, has an obligation to indemnify Cyclerion pursuant to Section 12.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

12.3 **Indemnification Procedures**. A Party seeking indemnification under Section 12.1 or Section 12.2 hereof (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of any claim, lawsuit, or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees, or agents intend to claim such indemnification. [***]. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

12.4 **Special, Indirect, and Other Losses.** EXCEPT FOR WILLFUL MISCONDUCT AND EXCEPT IN THE EVENT OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 10 OR SECTIONS 8.2 OR 8.8, AND EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, OR LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

12.5 **Insurance.** The Parties shall maintain insurance with creditworthy insurance companies against such risks and in such amounts as are usually maintained or insured against by other companies of established repute and in the same or a similar business.

Article 13
TERM AND TERMINATION

13.1 **Term.** This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect, on a Product-by- Product and country-by-country basis, in full force and effect until the expiration of the Royalty Term applicable to such Product and such country and will expire in its entirety upon the expiration of the last Royalty Term (such period, the "**Term**").

13.2 **Termination.**

(a) **Convenience**. At any time after the date one (1) year after the Effective Date, Akebia may terminate this Agreement in its entirety, by providing written notice to Cyclerion thereof, which termination will be effective one hundred eighty (180) days following the date of such notice, except, in the event that Akebia has received Regulatory Approval for a Product in any Major Country, such notice period will be [***] prior written notice.

(b) **Material Breach.**

(i) **Termination**. Either Party may terminate this Agreement at any time upon written notice to the other Party if the other Party is in material breach of this Agreement and such material breach is not cured within [***] after written notice thereof is delivered to the defaulting or breaching Party *provided*, *however*, if such breach is not reasonably curable within [***] and if the breaching Party is making a *bona fide* effort to cure such breach, such termination shall be delayed for a time period

to be agreed by the Parties in order to permit the breaching Party a reasonable period of time to cure such breach (but in no event will such additional time period be more than [***]. Any notice provided pursuant to this Section 13.2(b) shall identify with particularity the alleged breach and state the non-breaching Party's intent to terminate this Agreement if such breach is not cured. If the material breach described in the notice of such material breach solely pertains to one or more specific Major Countries, then the other Party may terminate this Agreement solely with respect to those Major Countries to which such breach pertains.

(ii) **Disputes Regarding Material Breach**. If the Parties reasonably and in good faith disagree as to whether there has been a material breach, then the breaching Party that disputes whether there has been a material breach may contest the allegation in accordance with Section 14.12, and the applicable cure period will toll upon the initiation of such dispute resolution procedures. If, as a result of such dispute resolution process, it is finally determined pursuant to Section 14.12 that the breaching Party committed a material breach of this Agreement, then the applicable cure period will resume and if the breaching Party does not cure such material breach within the remainder of such cure period (as such cure period may be extended pursuant to Section 13.2(b)(i)), then this Agreement will terminate effective as of the expiration of such cure period. This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the applicable cure period. Any such dispute resolution proceeding will not suspend any obligations of either Party hereunder and each Party will use reasonable efforts to mitigate any damages. Any payments that are made by one Party to the other Party pursuant to this Agreement pending resolution of the dispute will be promptly refunded if it is determined pursuant to Section 14.12 that such payments are to be refunded by one Party to the other Party. If, as a result of such dispute resolution proceeding, it is determined that the breaching Party did not commit such material breach (or such material breach was cured in accordance with this Section 13.2(b)(i)), then no termination of this Agreement will be effective, and this Agreement will continue in full force and effect.

(c) **Patent Challenge.** If Akebia or any of its Affiliates or Sublicensees commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Cyclerion Patent in any court, tribunal, patent office, or other proceeding in a country or other jurisdiction in the Territory (a "**Patent Challenge**"), then Cyclerion will have the right to terminate this Agreement on [***] written notice to Akebia; such termination of such license to be effective immediately following such notice period; *provided* that, if Akebia or its Affiliate or Sublicensee withdraws (or causes to be withdrawn) such Patent Challenge within [***] after being requested to do so by Cyclerion in writing (which termination notice will be deemed a request), then Cyclerion will have no right to terminate this Agreement pursuant to this Section 13.2(c). For the avoidance of doubt, Cyclerion may not terminate this Agreement pursuant to this Section 13.2(c) if Akebia or its Affiliate or Sublicensee is required by legal process to be joined as a party in any Patent Challenge by a Third Party. In addition, notwithstanding the foregoing, Cyclerion will have no right to terminate this Agreement pursuant to this Section 13.2(c) with respect to: (i) any affirmative defense or other validity, enforceability, or non-infringement challenge, whether in the same action or in any other agency or forum of competent jurisdiction advanced by Akebia, or any of its Affiliates or Sublicensees in response to any claim or action brought in the first instance by, on behalf of, Cyclerion or

any of its Affiliates or licensees; (ii) any Patent Challenge to the extent commenced by a Third Party that after the Effective Date acquires or is acquired by Akebia or any of its Affiliates or its of their business or assets, whether by stock purchase, merger, asset purchase or otherwise; *provided* that such proceeding commenced prior to the closing of such acquisition; or (iii) any Patent Challenge that is commenced by a Sublicensee; *provided* that Akebia demands that such Sublicensee withdraw such Patent Challenge promptly after Akebia becomes aware of such Patent Challenge and terminates the sublicense agreement with the applicable Sublicensee if such Sublicensee does not withdraw such Patent Challenge [***] after receipt of notice from Akebia.

(d) **Bankruptcy**. All rights and licenses now or hereafter granted by Cyclerion to Akebia under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Akebia pursuant to Section 8.1, are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by Cyclerion, Cyclerion agrees that Akebia, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Without limiting the generality of the foregoing, Cyclerion and Akebia intend and agree that any sale of Cyclerion's assets under Section 363 of the Bankruptcy Code shall be subject to Akebia's rights under Section 365(n), that Akebia cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Akebia's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Akebia. Further, each Party agrees and acknowledges that all payments by Akebia to Cyclerion hereunder, other than the royalty payments pursuant to Section 7.5 and the sales milestones pursuant to Section 7.4, do not constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or relate to licenses of intellectual property hereunder. Cyclerion will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property rights. Each Party acknowledges and agrees that "embodiments" of intellectual property rights within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples, and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Cyclerion Intellectual Property, and all information related to the Cyclerion Intellectual Property. If (A) a case under the U.S. Bankruptcy Code is commenced by or against Cyclerion, (B) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (C) Akebia elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, then Cyclerion (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

(1) provide Akebia with all such intellectual property rights (including all embodiments thereof) held by Cyclerion and such successors and assigns, or otherwise available to them, immediately upon Akebia's written request. Whenever Cyclerion or any of its successors or assigns provides to Akebia any of the intellectual property rights licensed hereunder (or any embodiment thereof) pursuant to this Section 13.2(d), Akebia will have the right to perform Cyclerion's obligations hereunder with respect to such intellectual property rights, but neither such provision nor such

performance by Akebia will release Cyclerion from liability resulting from rejection of the license or the failure to perform such obligations; and

(2) not interfere with Akebia's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property rights (including such embodiments), including any right to obtain such intellectual property rights (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

(ii) All rights, powers, and remedies of Akebia provided herein are in addition to and not in substitution for any and all other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to Cyclerion. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(1) the right of access to any intellectual property rights (including all embodiments thereof) of Cyclerion, or any Third Party with whom Cyclerion contracts to perform an obligation of Cyclerion under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import, export or other Exploitation of any Licensed Compound or Product; and

(2) the right to contract directly with any Third Party to complete the contracted work.

13.3 **Consequences of Termination.** In the event of a termination of this Agreement in its entirety for any reason, the following will apply:

(a) all rights and licenses granted by Cyclerion hereunder shall immediately terminate;

(b) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then Akebia shall, and hereby does effective as of the effective date of termination, grant Cyclerion an non-exclusive, royalty-free license, with the right to grant multiple tiers of sublicenses, under the Akebia Intellectual Property to Exploit in the Territory any Licensed Compound or Product;

(c) in the event there are any on-going Clinical Trials of the Products:

(i) the Parties shall work together in good faith to either adopt, and (A) if Cyclerion has become the sponsor in such Clinical Trial, then Cyclerion shall have the final decision-making authority with respect to, or (B) if Cyclerion has not become the sponsor in such Clinical Trial, then Akebia shall after good faith consultation with Cyclerion and taking into account reasonable suggestions from Cyclerion, have the final decision-making authority with respect to, a plan to (A) wind-down the Development activities in the Territory in an orderly fashion, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of the Products and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with

all applicable laws and regulations or (B) transfer such on-going Clinical Trials in the Territory to Cyclerion;

(ii) all costs and expenses incurred from the effective date of the termination notice in winding down the Development and Commercialization activities with respect to the Products shall be borne solely by Akebia, unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, in which case such costs and expenses shall be borne by Cyclerion;

(d) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then Akebia shall assign or cause to be assigned to Cyclerion or its designee (or to the extent not so assignable, Akebia shall take all reasonable actions as soon as practicable to make available to Cyclerion or its designee the benefits of) all Regulatory Submissions (including Regulatory Approvals) filed, submitted or received after the Effective Date solely for the Products in the Territory Controlled by Akebia or its Affiliates;

(e) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then Akebia shall, and hereby does, effective on the effective date of such termination, assign to Cyclerion all of Akebia's and its Affiliates' right, title, and interest in and to the Product Marks, including all goodwill therein, and Akebia shall promptly take such actions and execute such instruments, assignments, and documents as may be necessary to effect, evidence, register, and record such assignment, at Akebia's cost; *provided*, *however*, that the foregoing obligations shall not apply to any Product Marks that include, in whole or part, any corporate name or logo of Akebia or its Affiliates;

(f) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then upon Cyclerion's request, Akebia shall assign to Cyclerion any agreements with Third Party suppliers, contract research organizations, or other vendors that solely relate to the supply or sale of the Products in the Territory; *provided* that if any such contract between Akebia and a Third Party is not assignable to Cyclerion (whether by such contract's terms or because such contract does not relate specifically to the Product) but is otherwise [***] for Cyclerion to commence Developing or Commercializing the Products in the Territory, then Akebia shall reasonably cooperate with Cyclerion to negotiate for the continuation of services or supply from such entity for a period not to [***]; and

(g) Akebia shall have the right to sell in the Territory any remaining inventory over a period of [***] after the effective date of termination, or such other period as may be agreed by the Parties or required by applicable Regulatory Authorities (the "**Sell-Down Period**"). Notwithstanding the foregoing, if Akebia has not received Regulatory Approval for any Product before the effective date of termination or expiration of this Agreement, the Sell-Down Period shall be [***] after the effective date of termination or expiration of this Agreement. Unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, [***], Akebia shall report such inventory as of the end of the Sell-Down Period, and Cyclerion shall have the right to purchase from Akebia all or part of the inventory of Licensed Compound, Product, or any intermediate thereof held by Akebia as of the end of the Sell-Down Period at a price equal to the price paid by Akebia for the supply of such inventory.

13.4 **Cumulative Remedies.** Except as expressly stated otherwise herein, termination of this Agreement or other jurisdiction(s) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

13.5 **Accrued Obligations**. Except as set forth herein, any termination or expiration of this Agreement shall not relieve either Party of any obligation that has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein.

13.6 **Survival.** The terms of Sections 7.7 through 7.11, 8.5, 9.1(a), 9.1(b), 9.1(c)(i), 9.1(d), 11.4, 13.3, 13.4, 13.5, 13.6, 14.1, 14.2, 14.3, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12 14.13, 14.14 and Article 1, Article 10 and Article 12 shall survive any termination or expiration of this Agreement.

Article 14
MISCELLANEOUS

14.1 **Notices.** Any notice, request, demand, waiver, consent, approval, or other communication which is required or permitted to be given to any Party shall be in writing and shall be deemed given only if delivered to the Party personally, sent to the Party by registered mail, return receipt requested, postage prepaid, sent by a nationally recognized courier service guaranteeing next-day or second-day delivery, charges prepaid, or by email with affirmative confirmation of receipt, in each case addressed to the Party at its address set forth below, or at such other address as such Party may from time to time specify by notice given in the manner provided herein to the Party entitled to receive notice hereunder:

If to Akebia, to:
Akebia Therapeutics, Inc.
245 First Street
14th Floor
Cambridge, MA 02142
Attention: [***]
Email: [***]

with a copy (which shall not constitute notice) to:
Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: [***]
Email: [***]

And

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: [***]
Email: [***]

If to Cyclerion, to:

Cyclerion Therapeutics, Inc.
245 First Street
Riverview II, 18th Floor
Cambridge, MA 02142

Attention: [***]

with a copy (which shall not constitute notice) to:

Cyclerion Therapeutics, Inc.
245 First Street
Riverview II, 18th Floor
Cambridge, MA 02142
Attention: [***]

14.2 **Entire Agreement; Amendment.** This Agreement (including any Schedules or other attachments hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written statement may be used to interpret or vary the meaning of the terms and conditions hereof. This Agreement supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof, including that certain Confidential Disclosure Agreement between the Parties, dated August 18, 2020, which is hereby terminated. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

14.3 **Assignment.** Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided*, *however*, that a Party may make such an assignment without the other Party's prior written consent to (a) its Affiliate (b) to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of the business to which this Agreement relates or (c) in connection with a collateral assignment as a security to any lender or financial institution. Notwithstanding the forgoing, each Party shall have the right to sell, transfer, assign, delegate, pledge, encumber, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, such Party's rights to receive payments under this Agreement (including as part of a royalty monetization transaction) without the other Party's consent. Any attempted assignment or delegation in violation of this Section 14.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Cyclerion or Akebia, as the case may be. The permitted assignee or permitted transferee shall assume in writing all obligations of its assignor or transferor under this Agreement. Without limiting the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of Cyclerion, and the obligations of Cyclerion, including the payment obligations, shall run in favor of any such successor or permitted assignee of Cyclerion's benefits under this Agreement.

14.4 **Designation of Affiliates**. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

14.5 **Further Assurance**. Each of Cyclerion and Akebia agrees to duly execute and deliver, or cause to be duly executed or delivered, such further instruments and do and cause to be done such further acts, including the filing of additional assignments, agreements, documents, and instruments, as the other Party may at any time and from time to time reasonably request in connection with this

Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

14.6 **Force Majeure**. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a force majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable (but are not known for certain) as of the Effective Date. In addition, a force majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other force majeure event. The non-performing Party shall notify the other Party of such force majeure within [***] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably necessary and the non-performing Party shall use reasonable efforts to remedy its inability to perform.

14.7 **No Strict Construction; Headings.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation,” (c) the word “will” will be construed to have the same meaning and effect as the word “shall,” (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person’s or entity’s successors and assigns, (f) the words “herein,” “hereof,” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent,” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or

regulation thereof, (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," and (l) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)"). Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

14.8 **Relationship of the Parties.** It is expressly agreed that Cyclerion, on the one hand, and Akebia, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, or agency. Neither Cyclerion, on the one hand, nor Akebia, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

14.9 **Severability.** If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, then (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

14.10 **No Third-Party Beneficiaries.** Covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

14.11 **Governing Law.** This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

14.12 **Dispute Resolution.** In the event of any dispute under this Agreement, the Parties shall refer such dispute to the Executive Officers for attempted resolution by good faith negotiations within [***] after such referral is made. If the Executive Officers are unable to resolve the dispute within the time allotted, either Party may proceed as set forth below.

(a) **Alternative Dispute Resolution.** Any dispute that cannot be resolved pursuant to Section 14.12 above shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce [***] appointed in accordance with said Rules, [***]. The place of arbitration shall be Boston, Massachusetts and the language to be used in any

such proceeding (and for all testimony, evidence and written documentation) shall be English. The IBA Rules on the Taking of Evidence in International Arbitration shall apply on any evidence to be taken up in the arbitration.

(b) **Waiver of Jury Trial**. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED IN CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT HEREOF. NOTWITHSTANDING THE FOREGOING, NEITHER PARTY WAIVES ANY RIGHT TO A JURY PROCEEDING FOR THE DETERMINATION OF DAMAGES ARISING FROM ANY SUCH ACTION PROCEEDING OR COUNTERCLAIM.

(c) **Disputes Related to Patent Rights**. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the validity and enforceability of any Patent shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable Patent laws of such country, with a jury trial being however excluded. If such dispute involves such Patent matters and other matters, the arbitrators will have the right to stay the arbitration until determination of such Patent matters material to the resolution of the dispute as to the other matters is resolved.

(d) **Injunctive Relief**. Nothing contained in the Agreement shall deny either Party the right to injunctive relief, equitable relief, interim or provisional relief including a temporary restraining order, specific performance, preliminary or permanent injunction or other interim equitable relief from a court of competent jurisdiction in the context of a breach or threatened breach of any provision of the Agreement, *bona fide* emergency or prospective irreparable harm, or as reasonable and necessary to protect its legitimate interests. Such an action may be filed and maintained, notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding concerning a dispute if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

14.13 **No Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable law or otherwise available except as expressly set forth herein.

14.14 **Counterparts.** This Agreement may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Agreement. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[SIGNATURES PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their respective duly authorized officers.

CYCLERION PHARMACEUTICALS, INC.

By: /s/ Cheryl Gault
Name: Cheryl Gault
Title: Chief Operating Officer

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler
Name: John P. Butler
Title: Chief Executive Officer

By: /s/ David A. Spellman
Name: David A. Spellman
Title: Chief Financial Officer

Schedule 1.8

Assigned Trademarks

[***]

Schedule 1.30

Cyclerion Patents

Cyclerion Reference	Title	Country	Status	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date
[***]	[***]	[***]	[***]	[***]	[***]				
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Schedule 1.70

Licensed Compounds

[***]

Schedule 1.81

[***]

Schedule 3.3

Initial Development Plan

[***]

Schedule 4.1

Existing INDs

[***]

Schedule 5.3

Estimated Initial Supply

[***]

Schedule 9.2(a)

Control Transferring Patents

[***]

Schedule 9.2(c)

Non-Control Transferring Patent

[***]

Schedule 11.1(u)

Agreements relating to the Manufacture or supply of the Licensed Compounds and Products

Development Materials and related contracts:

[***]

Exhibit 31.1

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

I, Peter M. Hecht, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 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: July 29, 2021

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

Exhibit 31.2

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

I, Anjeza Gjino, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 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: July 29, 2021

By: /s/ Anjeza Gjino
Name: Anjeza Gjino
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

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

I, Peter M. Hecht, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Cyclerion Therapeutics, Inc. for the period ended June 30, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cyclerion Therapeutics, Inc.

Date: July 29, 2021

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

Exhibit 32.2

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

I, Anjeza Gjino, 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 June 30, 2021 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cyclerion Therapeutics, Inc.

Date: July 29, 2021

By: /s/ Anjeza Gjino
Name: Anjeza Gjino
Title: Chief Financial Officer (Principal Financial and Accounting Officer)