

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549
FORM 10-K**

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to _____

Commission file number: **001-38787**

CYCLERION THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Massachusetts
(State or other jurisdiction of
incorporation or organization)
245 First Street, 18th Floor, Cambridge, Massachusetts
(Address of principal executive offices)

83-1895370
(I.R.S. Employer
Identification No.)
02142
(Zip Code)

(857) 327-8778

Registrant's telephone number, including area code
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of the common stock held by non-affiliates of the registrant, as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$5.7 million, computed using the closing price on that day of \$2.91.

As of March 26, 2026, there were 4,330,314 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2026 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. “Business,” Part I, Item 1A. “Risk Factors,” and Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by 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:

- we are currently preparing a new potential product candidate for potential application in patients suffering from treatment resistant depression and we may not be successful in acquiring all license and other rights necessary to develop this technology, establish and successfully complete clinical studies, obtain necessary regulatory governmental approvals and successfully commercialize this product candidate;
- there is substantial doubt regarding our ability to continue as a going concern and we will need to raise capital in the near term in order to maintain our operations;
- we may be unable to access capital, capabilities, and transactions necessary to advance the development of the product candidate under evaluation and any future product candidates;
- there is substantial uncertainty regarding our future financial performance, potential revenues, expense levels, payments, cash flows, profitability, tax obligations, concentration of voting control, as well as the timing and drivers thereof;
- there is uncertainty regarding the impact of government funding and regulation in the life sciences industry, particularly with regard to funding for new drug development, staffing levels at government agencies and healthcare reform generally;
- there may be substantial delays to timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching and commercializing the product candidate under evaluation and potential future product candidates;
- we may be unable to maintain our relationships with third parties, collaborators and our employees or execute our strategic priorities;
- we may fail to maintain our Nasdaq listing;
- there are significant risks in our investment in Tisento Therapeutics Inc. (“Tisento”) tied to Tisento developing, obtaining regulatory approval for, launching and commercializing its product candidates and such risks may negatively impact our investment in Tisento;
- there is uncertainty regarding any liquidity or monetizable value of our equity interest in Tisento, which faces all the risks of an early-stage pharmaceutical development company;
- there is uncertainty as to whether any future development, regulatory, and commercialization milestones or royalty payments provided for in the license agreement with Akebia Therapeutics, Inc. will be achieved;

- we are seeking to out-license our olinciguat technology and we may be unsuccessful in identifying and entering into a licensing agreement in which event we would not be able to receive future royalty and milestone payments for olinciguat;
- in connection with our recent license agreement with the Massachusetts Institute of Technology (the “MIT License Agreement”), we must maintain minimum royalty payments and meet certain milestones and fulfill other obligations in order to retain rights under the license rights granted under the MIT License Agreement (the “MIT License”);
- in connection with our recent Collaboration and Option to License Agreement with Medsteer SAS (the “Collaboration Agreement”), if we elect to exercise the right to license certain rights held by Medsteer, we must maintain minimum royalty payments and meet certain milestones and fulfill other obligations in order to retain rights under the license rights if exercised under the Collaboration Agreement;
- our product candidates and those we have sold to Tisento or out-licensed to Akebia have not been approved for sale by regulatory agencies and may not prove to meet safety and efficacy requirements and if Tisento, Akebia or any potential future licensees are unable to comply with U.S. and non-U.S. regulatory requirements, including any post-approval development and regulatory requirements, or our potential future product candidates are unable to comply with such requirements, our operating results may suffer;
- we, Tisento and our current licensee and potentially any future licensees may be unable to obtain reimbursement from the U.S. government and third-party payors for potential future product candidates if and when commercialized;
- if we are unable to attract and retain employees needed to execute our business plans and strategies and or manage the impact of any loss of key employees our financial condition and results of operations may suffer;
- our business may be negatively impacted if we are unable to obtain and maintain intellectual property protection for our own technology and licensed technology necessary for current and potential future product candidates;
- third parties may allege we infringe their intellectual property rights, or could seek to invalidate any intellectual property rights we own or have licensed to third parties, which could result in adverse outcomes;
- we may be impacted by trends and challenges in the markets affecting our potential future product candidates;
- we may be unable to compete with other companies that are or may be developing or selling products that are competitive with any potential future product candidates;
- a determination that we constitute an investment company under the Investment Company Act of 1940, as amended, and if we are required to register thereunder, could have a material adverse effect on us;
- a pandemic or natural disaster may disrupt our business, including our development activities, resulting in a material adverse effect on our financial condition and results of operations;
- other factors that are described in Part 1, Item 1A “Risk Factors” of this our Annual Report on Form 10-K; and
- we may fail to maintain effective internal controls over financial reporting.

You should refer to “Item 1A. Risk Factors” in this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new

information, future developments or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date following the date of this Annual Report.

You should read this report and the documents that we reference in this report, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless the context requires otherwise, references in this report to “Cyclerion,” the “Company,” “we,” “us,” and “our” refer to Cyclerion Therapeutics, Inc. and, where appropriate, our consolidated subsidiaries.

PART I

Item 1. Business

Overview and Strategy

We focus on building a pipeline of innovative therapeutics to address serious neuropsychiatric disorders with significant unmet medical need. Our current strategic focus is centered on the development of a novel therapeutic approach for neuropsychiatric conditions, with the lead indication being treatment-resistant depression (“TRD”), which we believe represents a substantial clinical and commercial opportunity.

Primary Focus on New Potential Treatment for Treatment Resistant Depression (“TRD”)

Over the past year, we have refined our strategic direction toward programs that combine established pharmacologic agents with enabling technologies designed to improve precision, reproducibility, and patient outcomes. As part of this strategy, Cycleron has evaluated multiple opportunities and prioritized CYC-126, an individualized therapy for TRD as our foundational development program.

- In September 2025, we entered into a license agreement with the Massachusetts Institute of Technology (“MIT”) for intellectual property supporting this program (the “MIT License Agreement”). Under the terms of the MIT License Agreement, MIT will be eligible to receive up to \$4.4 million upon the achievement of certain development, regulatory and sales milestone payments. MIT will also receive tiered royalties in a range of percentages in the low single digits based on future net sales of licensed products as set forth in the MIT License Agreement. Further, we are required to pay MIT varying percentages of income received as consideration for any sublicenses granted.
- In January 2026, we entered into a collaboration and option-to-license agreement with Medsteer SAS (“Medsteer”) to access certain technology, data assets, and technical know-how related to drug delivery and physiological monitoring. Under the terms of the Collaboration Agreement, the Company will pay to Medsteer a nominal upfront payment, a payment upon exercise of the Option, and Medsteer will be eligible to receive up to \$3.7 million upon the achievement of certain development, regulatory and sales milestone payments. Medsteer will also receive an annual royalty payment and royalties in a percentage in the low single digits based on future net sales of licensed products, subject to certain adjustments as set forth in the Collaboration Agreement.
- We are advancing development planning, regulatory strategy, and commercial positioning for this program and intend to initiate a Phase 2 proof-of-concept study in Australia in the second half of 2026.
- In February 2026, we received notice from the FDA confirming prior informal communications that CYC-126 will be regulated under the FDA’s Center for Drug Evaluation and Research (“CDER”), with the FDA’s Center for Devices and Radiologic Health (“CDRH”) providing input and reviews as applicable. We believe that the FDA feedback provided clear guidance that the Company believes will help enable an FDA IND submission. The FDA guidance supported continued advancement of the planned Phase 2 study design, leveraging FDA-approved anesthetics and their well-established nonclinical and clinical safety data.
- As a result, we expect to remain on track to initiate the Phase 2 study in the second half of 2026, with the first patient anticipated to be enrolled in Australia and U.S. enrollment expected to commence in the first half of 2027.
- We have also recently announced the formation of a Clinical Advisory Board with the appointment of five internationally recognized key leaders in neuropsychiatry anesthesiology clinical care, and clinical development. This advisory board will provide strategic guidance and support key decision making regarding clinical development as Cycleron seeks to advance CYC-126 for TRD and builds a pipeline across neuropsychiatric diseases.

CYC-126 is being developed as a potential anesthetic-based therapy for neuropsychiatric indications, including TRD. The system is designed to deliver anesthetic agents while monitoring brain activity to support

individualized dosing through a patient feedback loop. The Company believes this approach may provide a differentiated treatment option for patients with TRD.

CYC-126 consists of two generic intravenous anesthetic agents, propofol and dexmedetomidine, administered through a personalized delivery system intended to operate as a clinical decision support tool for an anesthesiologist. The treatment is expected to be delivered in a hospital-based setting, such as a procedure room or post-anesthesia care unit (“PACU”), followed by a short recovery period in the PACU.

Major depressive disorder (“MDD”) is a prevalent psychiatric illness characterized by episodes of depressed mood, cognitive disturbances, and diminished interest or pleasure in activities lasting for at least two weeks. A subset of patients with MDD who do not achieve an adequate response after at least two antidepressant treatments are considered to have treatment-resistant depression. It is estimated that more than one-third of patients with medication-treated MDD meet criteria for TRD, representing approximately 2.8 to 3 million adults in the United States. Patients with TRD experience higher hospitalization rates, increased suicide risk, greater psychiatric comorbidity, and limited effective treatment options.

Cyclerion’s development strategy for CYC-126 is intended to leverage existing clinical knowledge and safety data associated with approved anesthetic agents while integrating technology-enabled monitoring and delivery capabilities. We believe this integrated approach may support differentiated clinical performance and scalability in hospital-based treatment settings; however, substantial development, regulatory review, and investment will be required before commercialization, if any.

Propofol and dexmedetomidine have an established clinical safety database as widely used anesthetic agents. Additionally, several early-phase clinical studies have suggested that propofol may have rapid-acting antidepressant effects in patients with TRD. Cyclerion is developing CYC-126 to incorporate a proprietary, technology-enabled delivery approach designed to achieve and maintain specific electroencephalogram (“EEG”) states. The Company believes that controlled sedation may modulate communication among brain regions that are dysregulated in patients with TRD.

Cyclerion expects to initiate a multinational proof-of-concept, double-blind randomized controlled trial of CYC-126. The study is expected to be conducted in two parts, with the first portion focused on safety and pharmacodynamic effects and the second portion focused on safety and efficacy. The Company currently estimates that the first portion of the study could commence in the second half of 2026 and that both portions of the study could be completed over the subsequent two years.

In parallel with the advancement of our neuropsychiatric strategy, Cyclerion continues to evaluate opportunities related to our legacy soluble guanylate cyclase (“sGC”) stimulator assets, including potential collaborations, monetization opportunities, or other strategic transactions intended to maximize shareholder value.

To support execution of our strategy, we intend to seek additional capital through equity or other financing transactions. In February 2025, our registration statement on Form S-3 (the “Shelf Registration”) was declared effective by the U.S. Securities and Exchange Commission, providing flexibility to access the capital markets, subject to market conditions and other factors. Under current SEC regulations, because the aggregate market value of our common stock held by non-affiliates is less than \$75 million, the amount of securities we may sell under the Shelf Registration during any twelve-month period is limited to one-third of the aggregate market value of our voting and non-voting common equity held by non-affiliates. In addition to the Shelf Registration, we are also seeking to raise capital to begin Phase 2 trials and for general working capital purposes. There can be no assurance that our efforts to raise capital will be successful, in which event we would have to delay or abandon our plans to implement our strategy for the CY-126 program.

Cyclerion operates with a lean organizational structure and utilizes a combination of internal leadership and external consultants to advance our programs while managing operating expenses. Regina Graul, Ph.D., was appointed Chief Executive Officer and Director in August 2024 after previously serving as President. Rhonda Chicko serves as Chief Financial Officer. We may expand our leadership team and operational capabilities over time as our development programs advance.

Background

We were founded in 2018 to focus on the treatment of serious diseases with novel sGC stimulators in both the central nervous system (CNS) and the periphery. Since that time, our strategy for Cycleron has changed and our sGC assets zagociguat and CY3018 were sold in 2023 to Tisento, we out-licensed praligicuat in 2021. We also entered into a non-binding license option agreement for olinciguat in 2024 which was terminated in 2025. Our prior strategy to conduct research and development on sGC stimulators has been discontinued and we do not intend to internally pursue research and development or commercialization with any sGC asset. We are leveraging our legacy sGC stimulator assets with the goal of generating revenues through potential license agreements, which, if realized, would be used to help fund our strategic building plan and provide value to our stockholders.

The following table is a high-level summary of our historical sGC portfolio:

Program	Indication(s)	Description	Status
Zagociguat (CNS-penetrant)	MELAS syndrome (mitochondrial encephalopathy, lactic acidosis, and stroke-like episodes syndrome), cognitive impairment associated with schizophrenia, and Alzheimer's Disease with Vascular Pathology (ADV)	Zagociguat is a CNS-penetrant sGC stimulator that has shown rapid improvements across a range of endpoints reflecting multiple domains of disease activity, including mitochondrial disease-associated biomarkers.	Sold to Tisento as part of the Asset Purchase Agreement in July 2023. On January 8, 2026, Tisento announced completion of enrollment in PRIZM, a global phase 2b study of Zagociguat for the treatment of MELAS. Zagociguat received Fast Track designation in June 2025 from the U.S. Food and Drug Administration for the treatment of MELAS.
CY3018 (CNS-penetrant)	Neuropsychiatric disorders	CY3018 is a CNS-penetrant sGC stimulator in preclinical development that has potential for the treatment of neuropsychiatric diseases and disorders.	Sold to Tisento as part of the Asset Purchase Agreement in July 2023.
Praliciguat (peripheral)	Focal Segmental Glomerulosclerosis (FSGS)	Praliciguat is a systemic sGC stimulator that is licensed to Akebia for the treatment of a rare kidney disease.	Out-licensed to Akebia in 2021 and renegotiated terms effective December 2024. In December 2025, Akebia announced that the first patient has been dosed in a Phase 2 clinical trial of praligicuat. In February 2026, we received a \$1,000,000 milestone payment from Akebia tied to the commencement of the

			first human clinical trials.
Olinciguat (peripheral)	Cardiovascular diseases	Olinciguat is a vascular sGC stimulator	Cyclerion entered into an exclusive non-binding license option agreement in July 2024 but terminated it in 2025. Cyclerion is currently exploring potential license opportunities.

Research and Development Programs

The following table presents the status of sGC stimulator assets that are either licensed or plan to be licensed or optioned to other entities:

Program	Indication	Discovery	IND Enabling	Phase 1	Phase 2	Phase 3	Approval	
Olinciguat (peripheral)	Cardiovascular Indications	→						
Praliciquat (peripheral) <small>OUT-LICENSED TO Akebia</small>	Focal Segmental Glomerulosclerosis	→						

Akebia License Agreement

On June 3, 2021, we entered into a License Agreement with Akebia (the “Akebia License Agreement”) 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 known as praliciquat and other related products and forms thereof enumerated in the Akebia License Agreement. Pursuant to the Akebia License Agreement, Akebia will be responsible for all future research, development, regulatory, and commercialization activities for the out-licensed praliciquat products. In 2021, Akebia paid a \$3.0 million upfront payment to us upon signing of the Akebia License Agreement.

On December 13, 2024, we announced that Cyclerion and Akebia re-negotiated a mutually beneficial amendment to Akebia's exclusive license agreement for praliciquat, a systemic sGC stimulator. Under this new license amendment, we will receive \$1.75 million in amendment payments, of which \$1.25 million was paid in December 2024 and an additional payment of \$0.5 million is due in September 2025. In addition, Akebia is responsible for all intellectual property expenses associated with praliciquat at an earlier date than as originally agreed between the parties. On December 1, 2025, Akebia publicly announced that it has recently initiated Phase 2 clinical trials for the treatment of focal segmental glomerulosclerosis (“FSGS”) using Praliciquat. Pursuant to the terms of amendment, upon initiation (defined as first patient dosed) of a Phase 2 clinical trial in the U.S. for a product, a \$1.0 million development milestone payment would be due to us and this payment was received in February 2026. We are eligible to receive additional milestone cash payments of up to approximately \$557.5 million in total related to potential future development, regulatory, and commercialization milestone payments for praliciquat. In exchange for a reduction in certain development milestone payments, we are eligible to receive certain higher-tiered sales-based royalties ranging from mid-single-digits to twenty percent.

Unless earlier terminated, the Akebia License Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the last royalty term, which ends upon the longest of (i) the expiration of the patents licensed under the Akebia License Agreement, (ii) the expiration of regulatory exclusivity for such product, and (iii) 10 years from first commercial sale of such product. Akebia may terminate the Akebia License Agreement in its entirety or only with respect to a particular licensed compound or product upon 180 days’ prior written notice to

Cyclerion, subject to certain obligations to license back to Cyclerion licensed compounds and candidates and related assets. The parties also have customary termination rights, subject to a cure period, in the event of the other party's material breach of the Akebia License Agreement or in the event of certain additional circumstances.

In January 2026, Akebia announced that the first patient was dosed in a Phase 2 clinical trial evaluating praliguat for focal segmental glomerulosclerosis (FSGS), a rare kidney disease. The randomized, double-blind, placebo-controlled study is designed to evaluate the efficacy and safety of praliguat, an oral soluble guanylate cyclase (sGC) stimulator, in approximately 60 adult patients.

Cyclerion is not responsible for the conduct of this study, and there can be no assurance regarding the timing, outcome, or potential commercialization of praliguat.

Tisento Asset Purchase Agreement

On May 11, 2023, we entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with an investor group that included Peter Hecht (our former CEO), JW Celtics Investment Corp and JW Cycle Inc. which subsequently changed their names to Tisento Therapeutics Holdings Inc. ("Tisento Parent") and Tisento Therapeutics Inc. ("Tisento"). Upon the closing in July 2023, following receipt of approval by the Cyclerion stockholders of the transactions contemplated by the Asset Purchase Agreement, we sold to Tisento certain assets (the "Transferred Assets") and Tisento assumed certain liabilities relating thereto. In consideration for such sale and assumption, at the closing we received proceeds of \$8.0 million as cash consideration, \$2.4 million as reimbursement for certain operating expenses related to such assets for the period between signing and closing of the Asset Purchase Agreement, and shares of common stock of Tisento Parent comprising 10% of the then issued and outstanding equity securities of Tisento Parent immediately following such closing, subject to certain protections against future potential dilution.

Under the terms of the Asset Purchase Agreement, we agreed not to compete with Tisento through July 2028 either alone or directly or indirectly with or through any affiliate or third party, initiate investigational new drug ("IND")-enabling preclinical development, develop, commercially manufacture, commercialize, or otherwise exploit any compound or product that is (A) a CNS-penetrant sGC stimulator, (B) developed for the treatment of a program indication, and (C) reasonably expected to compete with any compound or product in a purchased program for the treatment of a program indication (any such compound or product, a "Cyclerion Competing Product") anywhere in the world, or (ii) license, convey, grant, or otherwise transfer any rights to any third party to initiate IND-enabling preclinical development, develop, commercially manufacture, commercialize, or otherwise exploit a Cyclerion Competing Product anywhere in the world.

On January 27, 2025, Tisento Therapeutics announced that the first patient had been dosed in its global Phase 2b PRIZM study. The study is investigating the impact of once-daily oral zagociguat treatment on fatigue, cognitive impairment, and other key aspects of the rare mitochondrial disease MELAS (Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like Episodes). In June 2025, Tisento announced that it had received from the U.S. FDA "Fast Track Designation" for MELAS, lactic acidosis and certain Stroke-like Episodes.

PRIZM – a Phase 2b Randomized, Placebo-Controlled Trial Investigating Zagociguat in MELAS – is evaluating the efficacy and safety of oral zagociguat 15 mg or 30 mg compared to placebo when administered once-daily for 12 weeks in participants with genetically and phenotypically defined MELAS. The PRIZM study has a crossover design, with two 12-week treatment periods separated by a 4-week washout period. All participants will receive zagociguat during one of the 12-week periods and placebo during the other. Participants who complete the study may be eligible for an open-label extension study. PRIZM is a global study that will enroll approximately 44 participants at mitochondrial disease centers of excellence in the U.S., Italy, Germany, United Kingdom, Australia, and Canada. See ClinicalTrials.gov (NCT06402123) for more information.

In January 2026, Tisento announced completion of enrollment in the global Phase 2b PRIZM clinical trial evaluating oral zagociguat for the treatment of mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes (MELAS). The study enrolled approximately 43 participants, and Tisento has indicated that top-line results are expected in the fourth quarter of 2026.

Cyclerion does not control the conduct of this study and cannot provide assurance regarding its outcome or timing.

Olinciguat

Olinciguat is a Phase 2, orally administered, once-daily, vascular sGC stimulator. On July 22, 2024, we entered into an Option to License Agreement (the “Option Agreement”) with a third party (the “Optionee”), pursuant to which the Optionee had an option (the “Option”) to enter into an exclusive license to olinciguat for human therapeutics, subject to certain carveouts. Under the terms of the Option Agreement, the Optionee paid us an Option fee of \$150,000 in August 2024 and subsequent fees totaling \$80,000 to extend the term of the Option Agreement. The Optionee originally could exercise the Option on or before March 20, 2025, which option period was ultimately extended through August 22, 2025. Thereafter, the parties had an additional 60 days to negotiate the terms of a definitive license agreement. The parties were unable to agree upon the terms of a license agreement and we were provided notice on October 23, 2025 that the Optionee was terminating the Option Agreement. We are currently exploring potential license opportunities for olinciguat.

Intellectual Property

We protect the intellectual property and proprietary technology that we believe is important to our business, including by pursuing and maintaining U.S. and foreign patents that cover our product candidates and compositions, their methods of use and the processes for their preparation, as well as any other relevant inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We expect to also rely on licenses for patented intellectual property owned by third parties.

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions, improvements and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

We have 22 issued U.S. patents, 12 pending U.S. patents applications and numerous foreign patents and pending patent applications related to our sGC programs. Patent families are filed either as utility U.S. patents or under an international patent law treaty (PCT) that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the 158 contracting states, followed by the process of entering national phase, which requires a separate application in each of the member states in which national patent protection is sought.

For our TRD strategy, we have licensed a patent application from MIT. We also hold an option to license certain technology owned by Medsteer, a leading technology provider of closed loop anesthesia delivery systems, under the Collaboration Agreement. The patent application licensed from MIT has not yet been granted. We intend to apply for certain U.S. and foreign patents related to our TRD product strategy.

The technology underlying our sGC patents and pending patent applications has been developed by us and was not acquired from any in-licensing agreement.

The intellectual property portfolios for our most advanced product candidates in the sGC space (praliciguat and olinciguat) are summarized below.

Praliciguat Patent Portfolio

Our praliciguat patent portfolio includes 14 U.S. issued patents, 9 pending U.S. patent applications, and numerous patents and pending patent applications in foreign jurisdiction.

One of the U.S. patents, US 9,481,689, which will expire in 2034, is directed to praliciguat and pharmaceutical compositions thereof. The term of this U.S. patent may be eligible for patent term extension as described below. Three other U.S. patents, US 8,748,442, US 9,139,564, and 10,189,809, expire in 2031, and provide

generic coverage of praliciquat and intermediates used in the preparation of praliciquat, as well as compounds related to praliciquat, respectively. A fifth U.S. patent, US 10,183,021 will expire in 2034 and is directed to the treatment of resistant hypertension with praliciquat or combinations of praliciquat and known anti-hypertensives. A sixth U.S. patent, US 10,639,308 will expire in 2034 and is directed to the treatment of diabetic nephropathy with praliciquat or combinations of praliciquat with other agents. The seventh U.S. patent, US 10,927,136 covers phosphorus prodrugs of praliciquat and will expire in 2037. The eighth U.S. Patent, US 11,389,449, is directed to the treatment of metabolic syndrome with praliciquat and will expire in 2038. The ninth U.S. Patent, US 11,357,777, is directed to the treatment of a severe form of liver disease named nonalcoholic steatohepatitis (NASH) with praliciquat and other compounds and will expire in 2039. The tenth to fourteenth U.S. Patents, US 11,319,308 (expiring in 2039), US 11,773,089 (expiring in 2037), US 11,274,096 (expiring in 2039), US 11,708,361 (expiring in 2039) and US 12,275,724 (expiring in 2039) are directed to the syntheses of praliciquat or of intermediates useful in the manufacture of praliciquat.

Two pending U.S. patent applications that, if issued, will expire in 2031 and 2034, respectively, provide generic coverage for praliciquat composition of matter. Two additional U.S. patent applications that, if issued, will expire in 2037 and 2039, respectively, provide coverage for methods of large-scale preparation of praliciquat. We also have a pending U.S. application directed to a praliciquat formulation, that, if issued, will expire in 2036. Another pending U.S. application is directed to phosphorous prodrugs of praliciquat and, if issued, will expire in 2037.

Another of the U.S. pending applications is directed to methods of treating diabetic nephropathy with praliciquat, and if issued, will expire in 2040 or later. Another of the U.S. pending applications is directed to the use of certain sGC stimulators, including praliciquat for the treatment of HFpEF in post-menopausal women and, if issued, will expire in 2042.

Furthermore, we have eight granted European patents expiring between 2031 and 2039. Each of these patents is validated in multiple countries or registered in multiple countries as a European Unitary Patent. We hold nine granted Japanese patents expiring between 2031 and 2040. We also have numerous patent applications pending in foreign jurisdictions.

Oliniciquat Patent Portfolio

Our oliniciquat patent portfolio includes 16 U.S. issued patents, five pending U.S. patent applications and numerous patents and pending applications in foreign jurisdictions.

One of the U.S. patents, US 9,586,937, which will expire in 2034, is directed to oliniciquat and pharmaceutical compositions thereof. The term of this U.S. patent may be eligible for patent term extension as described below. Three other U.S. patents, US 8,748,442, US 9,139,564, and US 10,189,809, expire in 2031, and provide generic coverage of oliniciquat, intermediates used in the preparation of oliniciquat, and compounds related to oliniciquat, respectively. The fifth U.S. patent, US 10,517,874, which will expire in 2034 is directed to the treatment of SCD using oliniciquat alone or in combinations with other therapeutic agents. The sixth and seventh U.S. issued patents, US 10,889,577, and US 11,572,358, will expire in 2037 and are directed to polymorphs of oliniciquat. The eighth issued patent, US 11,207,323, will expire in 2034 and provides coverage for stereoisomers of oliniciquat. Seven more U.S. issued patents, US 11,319,308 (expiring in 2039), US 11,773,089 (expiring in 2037), US 11,274,096 (expiring in 2039), US 11,834,444 (expiring in 2038), US 12,030,874 (expiring in 2039), US 12,247,025 (expiring in 2037), and US 12,275, 724 (expiring in 2039) are directed to the chiral syntheses of oliniciquat or the syntheses of intermediates useful in the manufacture of oliniciquat. The last U.S. issued patent, US 11,357,777, is directed to the treatment of NASH with oliniciquat and other compounds and will expire in 2039.

One pending U.S. patent application, if issued, will expire in 2037 and provides additional coverage for polymorphs of oliniciquat. Two pending U.S. patent applications, if issued, will expire in 2031 and 2034, respectively, and provides generic coverage for oliniciquat. One pending U.S. patent application is directed to processes and synthetic intermediates for preparing oliniciquat and, will expire in 2037. A fifth pending U.S. patent application is directed to the treatment of heart failure with preserved ejection fraction (HFpEF) in post-menopausal women with oliniciquat and other sGC stimulators. If issued, the corresponding patent will expire in 2042.

Furthermore, we have nine granted European patents expiring between 2031 and 2039 each of them validated in multiple countries or registered in multiple countries as Unitary European Patents; eight granted Japanese patents

expiring between 2031 and 2039; seven granted Chinese patents expiring between 2031 and 2039; and a large number of issued patents in other foreign jurisdictions, expiring between 2031 and 2039. We also have numerous pending patent applications in foreign jurisdictions. Some of these patents may be eligible for patent term extension or the foreign jurisdiction equivalent, depending on the jurisdiction.

Patent Term

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application, assuming that all applicable maintenance or annuity fees are paid. In the United States, and China, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the respective patent offices, in examining and granting a patent, or, in the US, the term may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in that country, and the validity and enforceability of the patent.

In addition, the term of a U.S. patent that covers an US Food and Drug Administration (FDA)-approved drug may be eligible for patent term extension under the Drug Price Competition and Hatch-Waxman Act, to account for some of the time the drug is under development and regulatory review after the patent is granted. For a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of an FDA-approved drug (drug substance or drug product), an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug. Some foreign jurisdictions, including Europe, Japan, and China, have similar patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency.

Trade Secrets and Proprietary Information

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect our proprietary information, including trade secrets and know-how, by establishing confidentiality agreements with our commercial partners, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our employees, consultants, scientific advisors and contractors. These agreements generally provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also typically provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. However, these agreements may be breached, and we may not have adequate remedies for any breach. We also take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government Regulation

United States Regulation

The FDA regulates medical products, including prescription drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and regulations requires the expenditure of substantial time and financial resources. Failure to

comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal by the FDA to approve applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, debarment, or civil or criminal investigations and penalties brought by the FDA, the Department of Justice, State Attorneys General, or other governmental entities.

The process required by the FDA before a drug may be approved and marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory and animal studies conducted in accordance with applicable regulations, including Good Laboratory Practices, or GLP, regulations and applicable requirements for the humane use of laboratory animals;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may commence;
- approval by an independent institutional review board ("IRB") to proceed with initiating the clinical trial at each corresponding investigational site.
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, GCPs and other clinical-trial related regulations to establish the safety and efficacy of the product for each proposed indication;
- preparation and submission to the FDA of an NDA;
- satisfactory completion of one or more FDA inspections such as pre-approval inspection(s) of the manufacturing facility or facilities at which the product, or components thereof, are made to assess compliance with current GMP;
- payment of user fees for FDA review of the NDA; and
- FDA acceptance, review and approval of the NDA, which may include an Advisory Committee review.

The development and approval process requires substantial time, effort and financial resources and the receipt and timing of any approval is uncertain.

Nonclinical and Clinical Trials in Support of an NDA

Before testing any drug product candidate in humans, the product candidate must undergo rigorous nonclinical testing. Nonclinical studies include laboratory evaluations of the product candidate, as well as in vitro and animal studies to assess the potential safety and efficacy of the product candidate. The conduct of nonclinical studies that determine the product safety information for administration to humans must comply with federal regulations and requirements, including GLP regulations. The sponsor must submit the results of the nonclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical study protocol, to the FDA as part of an IND, which must become effective before clinical trials in a given indication may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the content of the IND or the conduct of the proposed trial(s) as outlined in the IND prior to that time. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial(s) can proceed.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements. Each clinical trial must be reviewed and approved by an IRB for the sites at which the trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The IRB also approves the informed consent form, including a privacy statement, which must be provided to each clinical trial participant or his or her legal representative, and must monitor the clinical trial until completed.

Clinical trials are typically conducted in three sequential phases prior to approval, which may overlap or be combined:

- *Phase 1.* Phase 1 clinical trials generally involve a small number of healthy participants or disease-affected participants who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability and safety of the drug.
- *Phase 2.* Phase 2 clinical trials usually involve studies in a limited population of participants with a disease or disorder to evaluate the efficacy of the product candidate for specific indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks.
- *Phase 3.* Phase 3 clinical trials generally involve a larger number of participants at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, to establish the overall benefit/risk profile of the product and to provide an adequate basis for product approval by the FDA.
- *Phase 4.* Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be required to be conducted after approval to gain additional experience from the treatment of participants in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA. Failure to conduct the Phase 4 clinical trials per the plan required by the FDA could result in enforcement action or withdrawal of approval.

Progress reports detailing new information and changes such as the results of clinical trials, new nonclinical studies, new product quality data, or changes to manufacturing controls must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time, or the FDA may impose other sanctions on various grounds, including a finding that the research participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the requirements of the IRB or if the drug has been associated with unexpected serious harm to participants. There are also requirements related to registration and reporting of certain clinical trials and completed clinical trial results to public registries.

Submission and Review of an NDA

Assuming successful completion of the required nonclinical and clinical testing, the results of nonclinical studies and clinical trials, together with detailed information on the product's manufacture, composition, quality controls and proposed labeling, among other things, are submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications. The application must be accompanied by a significant user fee payment, which typically increases annually, although waivers may be granted in limited cases (e.g., for products that have received an Orphan Designation).

The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and may require additional nonclinical or clinical studies, or other information (e.g., product quality data or manufacturing controls) before it accepts the filing. If an NDA has been accepted for filing, which occurs 60 days after submission, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original NDAs, the FDA has ten months from the filing date in which to complete its review of a standard application, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process may be significantly extended by FDA requests for additional information and clinical data or clarification.

The FDA reviews NDAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with current GMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA typically will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities comply with current GMP. Additionally, the FDA will frequently inspect one or more clinical trial sites for compliance with GCPs and integrity of the data supporting safety and efficacy.

During the approval process, the FDA will also prepare an integrated benefit-risk assessment and determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of the drug outweigh the risks and to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS. A REMS that includes elements to assure safe use, or ETASU, can substantially increase the costs of commercializing a drug. The FDA could also require a special warning, known as a boxed warning, to be included in the product label in order to highlight a particular safety risk. Boxed warnings may limit the type of advertising for a drug. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, FDA will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug and is accompanied by specific prescribing information for specific conditions of use. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the submission identified by the FDA and may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either amend the NDA with data to address the raised concerns, resubmit the NDA addressing all the deficiencies identified in the letter, engage in dispute resolution with the FDA about the identified deficiencies in the CRL, or withdraw the application. Even with submission of this additional information, the FDA may ultimately decide that the re-submitted application does not satisfy the regulatory criteria for approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, though companies developing orphan drugs may be eligible for certain incentives, including tax credits for qualified clinical testing.

Generally, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active component parts for the same indication for seven years from the date of such approval, except in limited circumstances. Competitors, however, may receive approval of different active component parts for the same indication or obtain approval for the same active component parts for a different indication. If one of our product candidates designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity.

Expedited Review and Approval Application Process

The FDA has various programs that are intended to expedite development and approval of drugs intended for the treatment of serious or life-threatening diseases or conditions and that demonstrate the potential to address unmet medical needs.

An application may be eligible for a "fast track" designation for a product that is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. Fast track designation provides opportunities for more frequent interactions with the FDA review team and permits FDA to consider sections of the NDA on a rolling basis before the complete application is submitted.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy". A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor.

An application may be eligible for “accelerated approval” where the product candidate is intended to treat a serious or life-threatening illness and provides meaningful therapeutic benefit over existing treatments; applications eligible for accelerated approval may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA requires a sponsor to conduct confirmatory studies to verify the predicted effect on IMM or another clinical endpoint, and the product may be subject to expedited withdrawal procedures.

Once an NDA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if the FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. Under priority review, the FDA must review an application in six months, compared to ten months for a standard review. A product may be eligible for more than one expedited approval program. Even if a product qualifies for one or more of these programs, however, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, these expedited review pathways do not change the standards for approval and may not ultimately expedite the development or approval process.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA for approval of a generic or 505(b)(2) application that relies on the listed drug as protected by regulatory exclusivity.

An NDA for a new chemical entity may receive five years of exclusivity, whereby the FDA will not accept for filing, with limited exceptions, a product seeking to rely upon the FDA’s findings of safety or effectiveness for such new chemical entity. An ANDA containing a paragraph IV patent certification can be filed after four years. Alternatively, an NDA may obtain a three-year period of non-patent market exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for both drugs and biologics, and also unexpired Orange Book listed patents in the case of drugs. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims and some manufacturing and supplier changes, are subject to prior FDA review and approval. There also are continuing annual user fee requirements for marketed products and the establishments where such products are manufactured, as well as new application fees for certain supplemental applications. The FDA may impose a number of post-approval requirements as a condition of approval of an NDA, such as Phase 4 clinical trials or a REMS.

In addition, entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA

and such state agencies for compliance with current GMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from current GMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain current GMP compliance.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay product distribution and require significant time and financial expenditures. Later discovery of previously unknown safety issues with a product, including adverse events of unanticipated severity or frequency, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters of clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications, in accordance with the provisions of the approved label and FDA guidance. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Additionally, all promotional material must be truthful and non-misleading, and present balanced information regarding the risks and benefits of the drug product.

Other Regulatory Requirements

Outside the U.S., our abilities to develop and market a product are contingent upon receiving approval and ultimately marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from jurisdiction to jurisdiction. At present, foreign marketing authorizations are applied for at a national level, although within the E.U. registration procedures are available to companies wishing to market a product in more than one E.U. member state.

We are subject to U.S. federal and foreign anti-corruption laws. Those laws include the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. corporations and their representatives from offering, promising, authorizing, or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA encompasses certain healthcare professionals in many countries. We are also subject to similar laws of other countries that have enacted anti-corruption laws and regulations.

Pediatric Development

In the European Union, companies developing a new medicinal product must agree to a Pediatric Investigation Plan, or PIP, with the European Medicines Agency (EMA) and must conduct pediatric clinical trials in accordance with that PIP, unless a deferral or waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The MAA for the product must include the results of pediatric clinical trials conducted in accordance

with the PIP, unless a waiver applies or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Where the MAA includes the results of all pediatric studies conducted in accordance with the PIP and the results are reflected in the approved summary of product characteristics, the holder of a patent or supplementary protection certificate is entitled to receive a six-month extension of the protection under a supplementary protection certificate or, in the case of orphan medicinal products, the product is eligible for a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

In the US, under Pediatric Research Equity Act (PREA), a pediatric development plan is required to accompany an NDA for all drugs, except those receiving non-oncology Orphan Drug Designation. This may include waiver or deferral of pediatric studies. The Best Pharmaceuticals for Children Act (BPCA) also allows for agreement with FDA on a pediatric written request that, if fulfilled, may extend data exclusivity for the molecule for an additional 6 months.

We believe that our plans for a potential new drug candidate for TRD under consideration may be applicable for the treatment of pediatric patients.

Competition

Despite our belief that the potential product that we intend to develop and commercialize in TRD will be differentiated, we will face competition from many different sources. Potential competition includes major/specialty pharmaceutical, biopharmaceutical, device and biotechnology companies, academic institutions, governmental agencies and medical research organizations. Additionally, we would expect that, if approved, our product will compete with the standard of care and any new therapies that may become available in the future. Several biopharmaceutical companies have therapies in clinical development for TRD and we are aware that many more are investigating treatments for TRD (e.g., psychedelic-related therapies are currently in development for TRD but have not yet been approved).

TRD is a disease with high unmet need and is associated with multiple serious public health implications. The FDA and the EMA have adopted the most used definition of TRD (i.e., inadequate response to a minimum of two antidepressants despite adequacy of the treatment trial and adherence to treatment). A number of published sources estimate that at least 30% of persons with depression meet this definition. There are many treatment paradigms that have been employed for the management of TRD. In general, these treatment paradigms /therapies can be bucketed into categories of: pharmacotherapies, somatic therapies and psychotherapeutic approaches. It is well known that the majority of these treatments have serious limitations despite their benefit. Many companies have developed or are seeking to develop new treatments for TRD. Leading companies in TRD market include Janssen (Johnson & Johnson) with Spravato, alongside major pharmaceutical firms Eli Lilly, AbbVie, Pfizer, and Novartis. Specialized biotechs like Compass Pathways and Axsome Therapeutics are actively developing novel therapies, including psychedelic compounds and rapid-acting agents.

- **Pharmacotherapies:** antidepressants and antipsychotics indicated for use in major depressive disorder are frequently prescribed, combined or augmented with a second agent to treat TRD. Additionally, mood stabilizers (e.g. lithium) are utilized as treatments, alone or in combination for TRD. Only two pharmacotherapies are approved for TRD in the U.S.: Spravato (esketamine), marketed by Janssen (a subsidiary of Johnson & Johnson) and Symbyax (olanzapine/fluoxetine hydrochloride capsules), developed by Eli Lilly and Company.
- **Somatic Therapies:** multiple somatic therapies are used for the management of TRD such as electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), vagus nerve stimulation (VNS), and deep brain stimulation (DBS).
- **Psychotherapeutic Approaches:** manual-based psychotherapies are not proven to be efficacious as a standalone intervention in TRD, but their efficacy in combination with antidepressants has been noted.

The biopharmaceutical industry is highly competitive within and across therapeutic categories and indications. There are many public and private biopharmaceutical companies, universities, government agencies and other research organizations actively engaged in the research and development and commercialization of products that

may be similar to our product candidates or address similar markets. In addition, the number of companies seeking to develop and commercialize products and therapies competing with our product candidates is likely to increase. However, we seek to build our portfolio with key differentiating attributes to provide a competitive advantage in the markets we target. The success of all of our product candidates, if approved, will likely depend upon their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Many of our competitors may have greater financial resources and broader expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved medicines than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors could also compete with us in establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Competition can also impact Tisento (in which we hold an equity interest), as well as companies which we have out-licensed or seek to out-license our product candidates. To date, the product candidates we have sold to Tisento or out-licensed to Akebia are either in early stage clinical or pre-clinical stages or not yet received any approval allowing for the commercial sale of these product candidates.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We intend to depend on third-party contract manufacturing organizations, or CMOs, for all our requirements of raw materials, drug substance and drug products for clinical trials and nonclinical research. We intend to continue to rely on CMOs for the supply of our retained assets for all stages of clinical development and commercialization, as well as for the supply of any other product candidates that we may identify. We require all our CMOs to conduct manufacturing activities in compliance with current GMP requirements.

Human Capital Resources

As a small, innovative company, if in the future we elect to start growing our internal operations, our success will depend on attracting, retaining and motivating highly skilled and experienced scientific, medical and other personnel. We plan to provide compensation and benefits programs which may include competitive salaries, potential annual discretionary bonuses, stock awards, a 401(k) plan with employer match, healthcare and insurance benefits, health savings and flexible spending accounts, unlimited vacation time, among other benefits. Our employees will be further guided by our code of conduct and our cultural values of seeking to serve patients, acting with integrity, empowering people and innovating for solutions.

Employee Profile

As of December 31, 2025, we had one employee and several consultants, including our Chief Financial Officer. We may in the future seek to expand our employee base, hire additional consultants and also outsource certain functions to other firms.

Corporate Information

We were incorporated in the Commonwealth of Massachusetts on September 6, 2018. Our principal executive offices are located at 245 First Street, Riverview II, 18th Floor, Cambridge, MA 02142. Our telephone number is (857) 327-8778. Our common stock is listed on the Nasdaq Capital Market under the symbol "CYCN."

Available Information

Our internet website address is www.cyclerion.com. In addition to the information contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is www.sec.gov.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. In this section, we first provide a summary of the more significant risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Risk Factors Summary

Risks Related to our Financial Position and Capital Needs

- We are a biopharmaceutical company with a limited operating history and no products approved for commercial sale.
- We have incurred significant losses and have never generated revenue from product sales; we anticipate that we will continue to incur significant losses for the foreseeable future and may never be profitable.
- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding in the near-term, which may not be available on acceptable terms, if at all, to continue as a going concern and advance our current and any potential future product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or our operations altogether. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.
- We have in-licensed a product candidate for treatment resistant depression and our approach to the discovery and development of this and any future product candidates we may develop may never lead to marketable products.

Risks Related to Development and Clinical Testing of Our Products and Product Candidates

- We may encounter substantial delays in our activities, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities in the development of our compounds.
- We could encounter difficulties in enrolling participants in any future clinical studies, which could delay or prevent progress of our product candidates.
- We may be unable to obtain regulatory approval of clinical trials and product approval and unable to generate product revenue for any product candidate.
- Any of our current or future product candidates may cause side effects that may result in label restrictions.

- We may have to change our nonclinical or clinical study protocols due to regulatory reasons or unanticipated events, which could result in increased costs to us and could delay our development timeline.

Risks Related to Reliance on Licensees, Tisento and Third Parties

- There are risks in our investment in Tisento tied to Tisento developing, obtaining regulatory approval for, launching and commercializing its product candidates.
- There is uncertainty as to any liquidity or monetizable value of our equity interest in Tisento, a privately-held company, which faces all the risks of an early-stage pharmaceutical development company.
- Akebia may not be successful in developing and commercializing any therapies through its praliguat out-license with the Company.
- We may not be successful in entering into necessary licenses or collaboration agreements and maintaining such licenses, and we may enter into collaboration or license arrangements in the future that ultimately are not successful.
- We expect that we will continue to rely on third parties to conduct nonclinical and clinical studies and to manufacture drug supplies for our product candidates. If these third parties do not execute successfully, our business could be substantially harmed.

Risks Related to Intellectual Property

- We share confidential information with third-party vendors, including trade secrets and know-how, which increases the possibility that our confidential information will be misappropriated or disclosed.
- We may be unable to adequately protect our proprietary and licensed technologies or obtain and maintain issued patents that are sufficient to protect our product candidates.
- We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts.
- Third parties may infringe our intellectual property rights.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- We may not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.
- We may not be able to obtain additional protection under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates.
- We may be subject to damages resulting from claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers.

Risks Related to the Future Commercialization of our Potential Future Product Candidates

- If the market opportunities for our product candidates are smaller than we estimate, our revenue and ability to achieve profitability may be harmed.
- We may fail to comply with healthcare and other regulations and could face substantial penalties.
- Our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours.
- The impact of healthcare reform and other governmental and private payor initiatives, as well as the potential for reductions in federal government funding for development and clinical trials as well as funding for certain treatments may harm our business.
- Our prospects for success depend on our ability to attract, retain and motivate qualified personnel.

- We will need to expand our organization and we may experience difficulties in managing growth of our employee base.
- We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

Other Risks

- We could fail to maintain proper and effective internal controls and our ability to produce accurate and timely financial statements could be impaired.
- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; interruptions to our commercial operations, clinical trials or other operations; harm to our reputation; loss of revenue or profits; loss of sales and other adverse consequences.
- If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur.
- We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act, or the FCPA, and other worldwide anti-bribery laws.

Risks Related to the holders of Our Common Stock

- We have a relatively limited public float for our shares and our common stock market price may fluctuate widely.
- The market price of our common stock may fluctuate widely and you could lose all or part of your investment in our common stock as a result.
- Any future failure to comply with Nasdaq's current and proposed continued listing requirements could result in the delisting of our common stock.
- We have adopted anti-takeover provisions in our articles of organization and bylaws and are subject to provisions of Massachusetts law that may frustrate any attempt to remove or replace our current board of directors or to effect a change of control or other business combination involving our company.

Risks Related to Our Financial Position and Capital Needs

As we are a biopharmaceutical company with a limited operating history and no products approved for commercial sale, valuing our business and predicting our prospects are challenging.

We are a biopharmaceutical company that was incorporated in 2018. Our business was conducted within Ironwood Pharmaceuticals, Inc. prior to that time, and we had no history as an independent company prior to the completion of the separation which occurred in 2019. We are seeking to develop new products for treatment resistant depression. We have also developed a pipeline of sGC stimulators, but we have no products approved for commercial sale, and we have never generated revenue from product sales nor have Tisento or Akebia ever generated product sales from products incorporating our compounds. Our operating activities to date have been limited primarily to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, pursuing partnership opportunities and obtaining licenses we deem necessary for our treatment resistant depression candidate, and conducting early-stage clinical trials for our product candidates.

To date, we have not obtained marketing approval for any of our product candidates; engaged on our own or through a third party, in commercial scale manufacturing or conducted sales and marketing activities necessary for the successful commercialization of our product candidates. Our short operating history offers limited insight into our prospects for success or even viability. We expect our operating performance to fluctuate. We will encounter challenges frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields and we have not yet demonstrated an ability to successfully navigate such challenges. If we do not successfully address the challenges we face, our business, prospects, financial condition and results of operations will be materially harmed.

Our business has incurred significant losses and we anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated revenue from product sales and may never be profitable.

Our business has incurred operating losses due to costs incurred in connection with our research and development activities and general and administrative expenses associated with our operations. Our net losses for the years ended December 31, 2025 and 2024 were \$3.5 million and \$3.1 million, respectively. We expect to incur significant losses for at least the next several years, and for these losses to significantly increase, as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates.

Our ability to generate revenue from our current and any potential future product candidates and achieve profitability depends on our ability, alone or with strategic partners, to complete the development of, and obtain the necessary regulatory and essential pricing and reimbursement approvals to commercialize, our product candidates. We do not know when, if ever, we will generate revenues from sales of our product candidates.

Our expenses would increase beyond expectations if we are required by the FDA, the EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even if one or more of the product candidates that we develop is approved for commercial sale, we may never generate revenue in amounts sufficient to achieve and maintain profitability.

There is substantial doubt about our ability to continue as a going concern. We will need to raise additional funding in the near term, which may not be available on acceptable terms, if at all to continue as a going concern and advance our product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or operations altogether. Raising additional capital would dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

There is substantial doubt regarding our ability to continue as a going concern. As of December 31, 2025, we had unrestricted cash and cash equivalents of approximately \$3.2 million. Our management believes that such cash and cash equivalents will not be sufficient to fund our operating expenses and capital requirements through mid-2026, whether or not we curtail efforts with respect to certain of our current and future product candidates. We will require significant additional funding to advance any of our product candidates beyond the short term and to sustain our operations. In the event that we are unable to raise the capital necessary, we may need to curtail our operations or cease operations altogether. Because there is substantial doubt about our ability to continue as a going concern for a reasonable period of time, an investment in our common stock is highly speculative and holders of our common stock could suffer a total loss of their investment.

We may also seek to raise such capital through public or private financing of our securities, royalty financing or debt financing. Raising funds in the current economic environment is, and may in the future, continue to be challenging, and such financing may not be available in sufficient amounts or on acceptable terms, if at all. The terms of any financing may harm existing shareholders. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute the ownership of existing shareholders.

If we sell shares or other equity securities in one or more other transactions, or issue stock, stock options or other securities pursuant to our current equity plans, investors may be materially diluted by such subsequent issuances. We will need significant additional capital in the near term to continue our current plans. No assurance can be given that we will be able to obtain such funds upon favorable terms and conditions, if at all. Failure to do so could have a material adverse effect on our business. To the extent we raise additional capital by issuing equity securities, our stockholders would likely experience substantial dilution. We may sell common stock, preferred stock, convertible securities or other equity or convertible securities in one or more transactions that may include voting rights (including the right to vote as a series on particular matters), preferences as to dividends and liquidation, antidilution, and conversion and redemption rights, subject to applicable law, and at prices and in a manner we determine from time to time. Such issuances and the exercise of any convertible securities will dilute the percentage ownership of our stockholders and may affect the value of our capital stock and could adversely affect the rights of the holders of such stock, thereby reducing the value of such stock. Moreover, any exercise of convertible securities may adversely affect the terms upon which we will be able to obtain additional equity capital, since the holders of such convertible

securities can be expected to exercise them at a time when we would, in all likelihood, not be able to obtain any needed capital on terms more favorable to us than those provided in such convertible securities.

Incurring debt, if available, would result in increased fixed payment obligations, and we may agree to restrictive covenants, such as limitations on our ability to incur additional debt or limitations on our ability to acquire, sell or license intellectual property rights that could impede our ability to conduct our business. In the event we are unable to raise financing, we may need to reduce or cease operations.

We also intend to seek funds through collaborations, strategic alliances, or licensing arrangements with third parties. Such agreements may adversely impact retained rights to our assets, technologies, future revenue streams and programs, especially those that receive regulatory approval.

Risks Related to Development and Clinical Testing of Our Products and Product Candidates

Our approach to the discovery and development of product candidates for the treatment of serious diseases may never lead to marketable products.

The development of drug therapies presents unique challenges, including an imperfect understanding of the biology, a frequent lack of translatability of nonclinical study results in subsequent clinical trials and dose selection, and the product candidate having an effect that may be too small to be detected using the outcome measures selected in clinical trials or if the outcomes measured do not reach statistical significance. Our future success is highly dependent on the successful development of our technology and our current and any potential future product candidates. The scientific evidence to support the feasibility of developing our current product candidates is both preliminary and limited. If we do not successfully develop and commercialize product candidates, we will not become profitable and the value of our common stock may decline.

Research and development of biopharmaceutical products is inherently risky. We may encounter substantial delays in our activities, including our planned clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities in the development of products to treat patients with serious diseases.

Our business depends heavily on the successful development, clinical testing, regulatory approvals and commercialization of our lead product candidate for treatment resistant depression, praliguat (out-licensed to Akebia), any potential future out-licensing of olinciguat, and any future potential product candidates we may acquire or license as well as both the Transferred Assets product candidates we have sold to Tisento. Any of our current or potential product candidates will require regulatory approval.

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

In the event of difficulties in enrolling participants in any clinical studies conducted on our product candidates, those clinical trials could be delayed or prevented from proceeding.

Identifying and qualifying participants to participate in any clinical studies of our product candidates would be critical to the success of those clinical trials. The timing of any clinical studies will depend in part on the speed at which participants can be recruited to participate in testing these product candidates. Estimates of the prevalence of target indications may vary considerably. Determining the incidence of these conditions, including in specific geographies or demographic groups, would be challenging. The lower the actual prevalence of these conditions, the more challenges would be encountered enrolling participants in those clinical studies, which could delay development of those product candidates. Clinical trial enrollment may also encounter difficulties for a variety of other reasons. The number of participants eligible for a clinical trial may be substantially limited by stringent eligibility criteria in a study protocol, such as the inclusion of biomarker-driven identification or other highly specific criteria related to stage of disease progression or to specific patient reported outcome measures. The number of participants required to power the statistical analysis of the study's endpoints may be very large leading to an extended enrollment period. Issues such as the proximity of participants to a study site, the complexity of the study design, the ability to recruit investigators with appropriate skill and experience, competing clinical studies for similar therapies or targeting similar participants, perceptions of the benefit-risk profile of the product candidate relative to other available therapies or product candidates, and ability to obtain and maintain institutional review board ("IRB"), or ethics committee ("EC") approvals and participant consents all could have a substantial impact on the timing of clinical trial enrollment. If sufficient participants cannot be enrolled in clinical studies in a timely way, obtaining study results would be delayed, which may harm our business, prospects, financial condition and results of operations.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we, Tisento, Akebia and any other future licensees, as applicable, are ultimately unable to obtain regulatory approval for the product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

A product candidate cannot be commercialized until the appropriate regulatory authorities have reviewed and approved the product candidate. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors, including the type and complexity of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application for review or may decide that data are insufficient for approval and require additional nonclinical, clinical, or other information (e.g., product quality data or manufacturing controls). No regulatory approval for any of our product candidates we own, licensed to Akebia or sold to Tisento has been requested or obtained, and it is possible that none of these existing product candidates or any product candidates we or our licensees or Tisento may seek to develop in the future will ever obtain regulatory approval.

Any ongoing clinical studies may not be completed on schedule, and any planned clinical studies may not begin on schedule, if at all. The completion or commencement of clinical studies can be delayed or prevented for a number of reasons, including, among others:

- the FDA or other regulatory bodies may not authorize us or our investigators to commence planned clinical studies, or require that ongoing clinical studies be suspended through imposition of clinical holds;
- negative results from ongoing studies or other industry studies involving product candidates modulating the same or similar mechanism of action;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or contract research organizations ("CRO"), and clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining EC or IRB approval(s) to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling participants in clinical studies, the proximity of participants to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the

availability of approved effective treatments for the relevant disease and competition from other clinical study programs for similar indications;

- severe or unexpected drug-related side effects experienced by participants in a clinical study;
- the presence of unanticipated metabolites in participants in a clinical study may require considerable nonclinical and clinical assessment;
- we, our licensees or Tisento may decide, or regulatory authorities may require the conduct of additional clinical studies or abandonment of product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical study;
- the FDA or other regulatory bodies may disagree with a clinical study's design and the interpretation of data from clinical studies, or may change the requirements for approval even after it has reviewed and commented on the design for clinical studies;
- reports from nonclinical or clinical testing of other competing candidates that raise safety or efficacy concerns;
- cutbacks in funding for the FDA may result in delays in reviewing and approving applications; and
- difficulties retaining participants who have enrolled in a clinical study but may be prone to withdraw due to rigors of the clinical studies, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, our licensees, Tisento, the FDA or other comparable authorities, the IRBs or ECs overseeing a clinical study, a data and safety monitoring board overseeing the clinical study, or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require undertaking corrective action, including in response to the imposition of a clinical hold;
- unforeseen safety issues, including any that could be identified in ongoing studies, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical studies.

Our product candidates may cause side effects or adverse events that are presented in the product labeling approved by regulatory authorities. Some may result in label restrictions.

Our current and any potential future product candidates may cause serious side effects which could cause us, our licensees, Tisento, or regulatory authorities to interrupt, delay or halt clinical studies and could result in restrictive label language or delay or denial of regulatory approval.

Changes in regulatory requirements, FDA guidance or unanticipated events during nonclinical studies and clinical studies of our product candidates, which may result in changes to nonclinical or clinical study protocols or additional nonclinical or clinical study requirements, which could result in increased costs and could delay development timelines.

Changes in regulatory requirements, FDA guidance or unanticipated events during nonclinical studies and clinical studies may force amendment to nonclinical studies and clinical study protocols or the FDA may impose additional nonclinical studies and clinical study requirements. Amendments or changes to clinical study protocols would require resubmission to the FDA and IRBs for review and approval, which may increase the cost or delay the

timing or successful completion of clinical studies. Similarly, amendments to nonclinical studies may increase the cost or delay the timing or successful completion of those nonclinical studies. In the event of delays in completing, or the termination of, any of nonclinical or clinical studies, or if it is required that additional nonclinical or clinical studies be conducted, the commercial prospects for product candidates may be harmed and our ability to generate product revenue will be delayed for those product candidates we retain our out-license or to realize value in our equity position in Tisento.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that there will be success in obtaining regulatory approval of our product candidates in other jurisdictions.

In order to market any product outside of the United States, compliance with the numerous and varying safety, efficacy and other regulatory requirements of other countries is required. Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that obtaining or maintaining regulatory approval in any other jurisdiction will be possible, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or other comparable foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical or clinical studies, as studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States, as well as other risks. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price intended to be charged for a product candidate is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs and could delay or prevent the introduction of product candidates in certain countries. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair the ability to market product candidates in such countries. Any such impairment would reduce the size of the potential market, which could have a material adverse impact on our business, prospects, financial condition and results of operations.

Data/market exclusivity may be more limited than we expect based upon the competitive landscape and other factors outside of our control that may occur during development or after approval.

There are many types of data/market exclusivity mechanisms that we or our licensees may seek to secure for our product candidates. Many of these have risk of loss of exclusivity if the competitive landscape changes or regulations are revised. If we, our licensees or Tisento seek and are awarded orphan drug designation in the US and/or the EU based upon criteria in effect at the time, this designation may be rescinded if a similar drug or another therapy that confers a significant benefit over these product candidates is subsequently approved. If these product candidates were to fail to obtain orphan drug status, or lose such status after it is obtained, or the marketing exclusivity that such status provides, our business, prospects, financial condition and results of operations could be materially harmed. There are other types of data/market exclusivity rights granted after approval that may not confer exclusivity anticipated if the competitive landscape changes and our business, prospects, financial condition and results of operations could be materially harmed.

Risks Related to Reliance on Licensees, Tisento and Other Third Parties

We may not succeed in our pursuit of capital, capabilities, and transactions for the development and commercialization of our future clinical stage assets, which would affect our financial condition.

We are seeking capital, capabilities, and transactions to advance the development of our product candidate for treatment resistant depression and other product candidates we may acquire rights to in the future. There can be no assurance that this process will result in any effective negotiations toward, reaching terms of, executing agreements relating to, or completing any transaction or that any such transaction will be successful. Failure to complete any of the

foregoing efforts would materially adversely affect our business, prospects, financial condition and results of operations.

Akebia may not be successful in developing any therapies through the praliguat out-license and we may not realize any future revenue from the out-license.

On June 3, 2021, we entered into the Akebia License Agreement 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 praliguat and other related products and forms thereof enumerated in such agreement. Under the agreement, Akebia is responsible for all research, development, regulatory, and commercialization activities for certain products. On December 13, 2024, we and Akebia entered into Amendment #1 to License Agreement (the “2024 Amendment”) to the original Akebia License Agreement. Under the terms of the 2024 Amendment, Akebia paid the Company (i) \$1.25 million in December 2024 and an additional \$0.5 million in September 2025. In addition, Akebia has agreed to assume control of the preparation, filing, prosecution and maintenance of certain Cycleron patents, and the expenses associated therewith, at an earlier date than as originally agreed between the parties. The parties have agreed to the reduction of certain development milestones and the increase of certain royalty rates on net sales and sublicense income. Pursuant to the terms of the Akebia License Agreement, as amended, Akebia will pay Cycleron tiered royalties ranging from mid-single digit to twenty percent of net sales. Cycleron’s obligations to deliver certain drug products have also ceased. The agreement may be terminated by either party in the event of a material breach by the other party or by us in the event of certain patent disputes. There can be no assurances that the agreement will result in any therapies or that it will not be terminated prior to the realization by us of any remaining eligible revenues or that Akebia will be able to successfully bring any of the licensed product candidates to market due to financial limitations or other business factors in the future or if Akebia is unable to raise additional capital on favorable terms, if at all. Akebia may at any time terminate the Akebia License Agreement upon 180 days written notice, subject to Akebia’s obligation to grant Cycleron a non-exclusive, royalty-free license, with the right to grant multiple tiers of sublicenses, to certain licensed compounds or products as defined in the Akebia License Agreement as well as certain rights to regulatory submissions, product trademarks, contracts with third party suppliers and certain other rights.

Tisento may not be successful in developing any therapies and we may not realize any future value from the Tisento common stock we received under the Asset Purchase Agreement with Tisento.

Our investment in Tisento is subject to all of the risks associated with an earlier stage biotechnology company. The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that Tisento’s technology, development experience and scientific knowledge provide it with competitive advantages, it may face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of similar products. Any investigational products that Tisento may successfully develop and commercialize will compete with new immunotherapies that may become available in the future. As a result, our investment in Tisento is risky and our equity interest in Tisento could be significantly diluted in the future if Tisento seeks to raise additional capital or is unable to raise additional capital on favorable terms, if at all. If Tisento suffers adverse effects, it may not be able to continue as a going business concern, and we may lose our entire investment. Tisento is a privately-held company and there is no public market for its securities. As a result, it may be difficult to sell any of our securities position in Tisento in the near term, if at all.

We lack operational control over Tisento.

Our investment in Tisento represents a minority or passive stake and we may have little to no participation, input or control over the management, policies, and operations of Tisento. Further, we may lack sufficient ownership of voting securities to impact, without the vote of additional equity holders, any matters submitted to stockholders or members of such business for a vote. There is inherent risk in making minority equity investments in companies over which we have little to no control. Without control of the management and decision-making of these businesses, we cannot control their direction, strategy, policies and business plans, and we may be powerless to improve any declines in their performance, operating results and financial condition.

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

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

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

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

We expect in the future to rely on third parties to conduct any nonclinical or clinical studies for any existing or potential future product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, necessary regulatory approvals for or commercialization of any potential future product candidates may not be obtainable and our business could be substantially harmed.

We do not have the infrastructure or internal resources and capabilities to independently conduct nonclinical or clinical studies. We expect to rely on contract laboratories, medical institutions, clinical investigators, licensees and other third parties, such as CROs, to conduct nonclinical studies on any future discovery compounds and product candidates and clinical studies on product candidates. We expect to rely heavily on such parties for execution of nonclinical and clinical studies and as a result that we will only be able to control certain aspects of their activities. As a result, we expect we will have limited direct control over the conduct, timing and completion of our nonclinical and clinical studies and the management of data developed through these studies. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities, become financially distressed or form relationships with other entities, some of which may be our competitors.

These factors may materially impede the willingness or ability of third parties to complete quality nonclinical and clinical studies and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we may

be responsible for ensuring that each of any future nonclinical and clinical studies is conducted in accordance with any applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on CROs and other third parties does not necessarily relieve us of our regulatory responsibilities. We, and any future CROs and other third parties are required to comply with regulations and guidelines, such as good laboratory practices (“GLPs”), good clinical practices (“GCPs”), and current Good Manufacturing Practices. These regulations are enforced by the FDA and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces compliance to regulations through periodic inspections of clinical study sponsors, principal investigators, and third parties. If the FDA determines there was a failure to comply with the regulations the clinical data generated in any clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require the performance of additional clinical studies before approving any marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any potential future nonclinical studies, clinical studies or product manufacturing will comply with these regulations. Our failure or the failure of our CROs or other third parties to comply with these regulations may require the repeat of those clinical studies, which would delay the regulatory approval process and could also result in enforcement action up to and including civil and criminal penalties.

Although we or our current licensee or any future licensees may design or approve the designs of our product candidate clinical studies, CROs and other third parties conduct those clinical studies. As a result, many important aspects of the execution of the development programs for our product candidates may be outside of our direct control. In addition, the CROs, or other third parties, may not perform all of their obligations under arrangements with us or our licensees or in compliance with regulatory requirements, but we may remain responsible and are subject to enforcement action that may include civil penalties and criminal prosecution for any violations of FDA laws and regulations during the conduct of clinical studies. If the CROs, or our licensees, do not perform clinical studies in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our product candidates may be delayed, or our development program materially and irreversibly harmed. We may not be able to control the amount and timing of resources these CROs or our licensees devote to our clinical products.

If any relationships with these third-party CROs terminate, arrangements with alternative CROs may not be achievable. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to required clinical protocols, regulatory requirements or for other reasons, any clinical studies such CROs are associated with may be extended, delayed or terminated, and required regulatory approval for or successfully commercialization of our product candidates may not be obtainable. As a result, we believe that our financial results and the commercial prospects for our product candidates in the approved indication would be harmed, our costs could increase and our ability to generate revenue could be delayed or lost.

Except as out-licensed, we must rely completely on third-party suppliers to manufacture any nonclinical and clinical drug supplies for our product candidates, and we intend to rely on third parties to produce commercial supplies of any product candidates that are approved.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture the drug supply of our current or any potential future product candidates, for use in the conduct of our nonclinical and clinical studies. We lack the internal resources and the capability to manufacture any product candidates on any scale. We expect to depend on third-party contract manufacturing organizations, or CMOs, for all our requirements of raw materials, drug substances and drug product for any future nonclinical studies and clinical trials. We do not have long-term supply agreements in place with any CMO and we expect that any potential future product candidates will be individually contracted under a services agreement on a purchase order basis. We expect to rely on CMOs for the supply of later-stage development and commercialization, as well as for the supply of any other discovery compounds or product candidates that we may identify, and we may not be able to enter into long-term supply agreements with such CMOs on favorable terms. As a further result, we are subject to price fluctuations for any clinical drug supplies. If the prices charged by these CMOs increase, our business, prospects, financial condition and results of operations could be materially harmed. We expect in the future to apply industry risk management practices to minimize the impact to nonclinical and clinical timelines associated with delays to our clinical supplies. However, these delays could still lead to clinical trials delays that could adversely impact our business.

In addition, any facilities which may be used by contract manufacturers to manufacture the active pharmaceutical ingredient and final drug product must complete a pre-approval inspection by the FDA and other comparable foreign regulatory agencies to assess compliance with applicable requirements, including current GMP, after we submit our new drug application, or NDA, or relevant foreign regulatory submission to the applicable regulatory agency. If the FDA or an applicable foreign regulatory agency determines now or in the future that these facilities are noncompliant, we may need to find alternative manufacturing facilities, which would impede our ability to develop, obtain regulatory approval for or market our product candidates.

Our anticipated reliance on third parties requires us to share our confidential information, including trade secrets and know-how, which increases the possibility that our confidential information will be misappropriated or disclosed.

Because we seek to involve third party licensees and collaborators on current and potential future product candidates, we expect we will rely on third parties to manufacture our product candidates, and because we expect to collaborate with various CROs and other third parties to conduct our nonclinical studies and clinical trials, we must, at times, share our trade secrets or know-how with them. We seek to protect our confidential information, including know-how and trade secrets, in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors and consultants prior to beginning our collaborations or disclosing confidential information to such parties. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets and know-how. Despite these contractual provisions, the need to share our confidential information with third parties increases the risk that confidential information such as trade secrets and know-how becomes known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our confidential information including know-how and trade secrets, a competitor's discovery of our confidential information or other unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Our Intellectual Property Rights

If we or our licensors, licensees or Tisento are unable to adequately protect proprietary technologies, or obtain and maintain issued patents that are sufficient to protect their respective product candidates, others could compete against us, our licensees and Tisento more directly, which would have a material adverse impact on our business, prospects, financial condition and results of operations.

Our success will depend in part on our licensors, licensees and Tisento's ability to obtain and maintain patent and other proprietary protection in the United States and other countries for commercially important technology, inventions and know-how related to our business, defend and enforce patents, should they issue, preserve the confidentiality of trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our product candidates and compositions, their methods of use and any other Inventions that are important to the development of our business.

We have 22 issued U.S. patents, 12 pending U.S. patents applications and numerous foreign patents and pending patent applications. Patent families are filed either as utility U.S. patents or under an international patent law treaty (PCT) that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the 158 contracting states, followed by the process of entering national phase, which requires a separate application in each of the member states in which national patent protection is sought. We also rely on patents issued to licensors providing patent licenses for our treatment resistant depression candidate.

See "Business — Intellectual Property." We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent positions of biotechnology and pharmaceutical companies, including ours, involve complex legal and factual questions, which in recent years have been the subject of much litigation, and, therefore, the issuance, scope, validity, enforceability and commercial value of any patent claims that we may obtain cannot be predicted with

certainty. Patent applications may not be granted as issued patents in any particular jurisdiction and, even if they do, these patents may not include claims with a sufficient scope to protect our product candidates or otherwise provide any competitive advantage.

Even if patent applications are issued, competitors and other third parties may infringe, misappropriate or otherwise violate patents and other intellectual property rights. We may not be able to prevent infringement, misappropriation or other violations of intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. To counter infringement or unauthorized use, filing infringement claims may be required, which can be expensive and time-consuming and divert the attention of management and key personnel from business operations.

Moreover, patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented in the United States and abroad. U.S. patents and patent applications may also be subject to interference, derivation, ex-parte reexamination, post-grant review, or inter-partes review proceedings, supplemental examination and challenges in district or other courts. Interference proceedings provoked by third parties or brought by us or our licensees may be necessary to determine the priority of inventions with respect to patents or patent applications. An unfavorable outcome could require ceasing the use of the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer a license on commercially reasonable terms. Involvement in litigation or interference proceedings may fail and, even if successful, may result in substantial costs, and distract management and other employees. Furthermore, an adverse decision in an interference or derivation proceeding can result in a third party receiving the sought-out patent right, which in turn could affect the ability to develop, market or otherwise commercialize our product candidates.

Patents may also be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices or courts. Such proceedings could result in revocation or amendment of patents in such a way that they no longer cover our product candidates or competitive products. In addition, such proceedings may be costly. Thus, any patents, should they issue, may not provide any protection against competitors.

Furthermore, though a patent, if it were to issue, is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide adequate protection to exclude competitors from making similar products. Even if a patent issues and is held to be valid and enforceable, competitors may be able to design around or circumvent our patents, such as by using pre-existing or newly developed technology or products in a non-infringing manner. If these developments were to occur, they could have a material adverse effect on our business, prospects, financial condition and results of operations.

Any litigation to enforce or defend patent rights, even if successful, would be costly and time-consuming and would divert the attention of management and key personnel from business operations. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend any patents, if and when issued, put those patents at risk of being invalidated, held unenforceable or not infringed, or interpreted narrowly. Such proceedings could also provoke third parties to assert counterclaims, including that some or all of the claims in one or more patents are invalid, not infringed or unenforceable. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions of a patent include allegations that someone connected with prosecution of the patent application that matured into the patent withheld relevant information from the U.S. Patent and Trademark Office, or the USPTO, or made a misleading statement, during prosecution of the patent application. In an infringement proceeding, a court may disagree with allegations and refuse to stop the other party from using the technology at issue on the grounds that patents do not cover the technology in question or may decide that a patent is invalid or unenforceable. An adverse result in any litigation, defense or post-grant proceedings could result in one or more patents being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim

proceedings or developments. If securities analysts or investors perceive these results to be negative, it would have a material adverse effect on the price of our common stock.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, there cannot be certainty that there is no invalidating prior art, of which we, our licensees and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, at least part, and perhaps all, of the patent protection on our product candidates could be lost.

If any patents, if and when issued, covering our product candidates are invalidated or found not infringing or unenforceable, our business, prospects, financial condition and results of operations could be materially harmed.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates, if approved.

Our success will depend in part on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. Other parties may allege that our product candidates or the use of our technologies or technologies licensed by us infringe or otherwise violate patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, materials, formulations, methods of manufacture or methods for treatment related to our product candidates. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our product candidates may infringe, or which such third parties claim are infringed by our technologies.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain and cannot be adequately quantified in advance. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either does not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our product candidates. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing our product candidates. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license.

Any of these risks coming to fruition could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property we own or license from third parties.

Our employee, consultants, non-academic outside scientific collaborators and other advisors enter into confidentiality and intellectual property assignment agreements with us or have entered into confidentiality and intellectual property assignment agreements with Ironwood or third parties licensing intellectual property to us. We seek to have inventions assigned to us by the parties rendering services whenever possible. Our in-bound licenses seek

to insure that all of the intellectual property licensed to us is owned by the licensor. However, we may not be able to enter into these agreements with all parties (for example with academic collaborators) or these agreements may not be honored and may not effectively assign intellectual property rights to us.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, or we may have to in-license intellectual property owned by another party. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies and patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions over the lifetime of owned patents and applications. For in-bound licensed intellectual property rights, failure to maintain compliance with such requirements would adversely impact our rights as regards those patents and applications. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors or other third parties might be able to enter the market earlier than would otherwise have been the case and this circumstance could have a material adverse effect on our business, prospects, financial condition and results of operations.

We and our licensees and Tisento may not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications and we may not timely file foreign patent applications. Thus, for each of the patent families that are believed to provide coverage for our product candidates, we, and our licensees, will need to decide whether and where to pursue protection outside the United States. Filing and prosecuting patent applications and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and so it is unlikely to pursue and maintain patents in all countries worldwide. As such, competitors may use technologies in jurisdictions where patent protection is not pursued and obtained to develop their own products.

The laws of some foreign countries may not protect intellectual property rights to the same extent as the laws of the United States. Consequently, it may not be possible to prevent third parties from practicing our inventions in all countries outside the United States even if there is a patent in that jurisdiction. Further, a competitor may export otherwise infringing products to territories where patent protection exists, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even pursuing and obtaining issued patents in particular jurisdictions, patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology or pharmaceuticals. This could make it difficult to stop the infringement of patents, if obtained, or the misappropriation of or marketing of competing products in violation of other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes.

Accordingly, patent protection might not be sought in certain countries, and there will not be a benefit of patent protection in such countries.

Proceedings to enforce patent rights in foreign jurisdictions could result in substantial costs and divert efforts and attention from other aspects of our business, could put patents at risk of being invalidated or interpreted narrowly, could put patent applications at risk of not issuing, and could provoke third parties to assert claims. We, or our licensees, may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that developed or licensed.

If we, or our licensees, do not obtain additional protection under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates, our business, prospects, financial condition and results of operations may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of the U.S. patents owned may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent term extension as compensation for patent term lost during the FDA regulatory review process. A maximum of five years can be restored to the eligible patent. In all cases, the total patent life for the product with the patent extension cannot exceed 14 years from the product's approval date, or in other words, 14 years of potential marketing time. However, an extension might not be granted because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If unable to obtain a patent term extension or the term of any such extension is less than we request, the duration of patent protection obtained for our product candidates may not provide any meaningful commercial or competitive advantage, competitors may obtain approval of competing products earlier than they would otherwise be able to do so, and our ability to generate revenues could be harmed.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has enacted and implemented wide-ranging patent reform legislation: the Leahy-Smith America Invents Act, or the America Invents Act. The America Invents Act includes a number of significant changes to U.S. patent law. These provisions affect the way patent applications will be prosecuted and may also affect patent litigation. It is not yet clear what, if any, impact the America Invents Act will have on the operation of certain elements of our product candidates. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, prospects, financial condition and results of operations.

In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on these and other decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce any patents that may issue in the future.

We may be subject to damages resulting from claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers.

Our current employee and any employees we may hire in the future may have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We also engage and, in the future, intend to engage advisors and consultants who are concurrently employed at universities or who perform services for other entities.

We may be subject to claims that we or our employees, advisors or consultants or third parties from whom we license certain technologies have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. We may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would materially harm our commercial development efforts.

Risks Related to the Future Commercialization of Our Current or Potential Future Product Candidates

The incidence and prevalence for target patient populations of our current and any potential future product candidates we may acquire have not been established with precision. If the market opportunities for our current and potential future product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be harmed.

The incidence and prevalence for all the conditions we aim to address with our current and any potential future programs vary considerably. Projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates, if approved for sale for these indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would harm our results of operations and our business. Further, even if significant market share for our product candidates is obtained, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates, if approved, we may not be successful in commercializing those product candidates if and when they are approved.

We do not currently have an infrastructure for the sale, marketing, market access, patient service and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory authority outside the United States, we must build our sales, marketing, managerial and other non-technical capabilities, or arrange with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product candidate launch. If commercialization is delayed or does not occur, we would have prematurely or unnecessarily incurred such expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, any product candidate revenue or the profitability of that revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may fail to enter into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, or if we are unable to do so on commercially reasonable terms, we will not be successful in commercializing our product candidates if approved and our business, prospects, financial condition and results of operations will be materially harmed.

Even if we obtain regulatory approval for our product candidates, our product candidates may not achieve broad market acceptance by patients, physicians, healthcare payors or others in the medical community, which would limit the revenue that we generate from their sales.

The future commercial success of our product candidates, if approved by the FDA or other applicable regulatory authorities outside the United States, will depend upon the awareness and acceptance of our product candidates among the medical community, including patients, physicians and healthcare payors. If any of our product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians, healthcare payors and others in the medical community, we may not generate sufficient revenue to become, or remain, profitable. Market acceptance of our product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy and safety of our approved product candidates as demonstrated in clinical trials;
- the clinical indications and labeling claims for our product candidates that are approved;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or other applicable regulatory authorities;
- any restrictions on the use of our product candidates together with other medications or restrictions on the use of our products in certain types of patients;
- the prevalence and severity of any adverse effects associated with our product candidates;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the safety, efficacy, cost and other potential advantages of our approved product candidates compared to other available therapies;
- our ability to generate cost effectiveness data that supports a profitable price;•our ability to obtain sufficient reimbursement and pricing by third-party payors and government authorities;•the willingness of patients to pay out-of-pocket in the absence of sufficient payor coverage;•the effectiveness of our sales and marketing strategies; or
- publicity concerning our product candidates or competing products and treatments.

If our product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably. Price controls may be imposed in certain markets, which may harm our future profitability.

Market acceptance and sales of any approved product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and government authorities and may be affected by existing and future health care reform measures and cost-cutting measures at the federal and state level currently proposed for Medicaid and other programs. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require the provision of supporting scientific, clinical and cost-effectiveness data for the use of our product candidates to the payor. We or our partners may not be able to provide

data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our product candidates. In addition, in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our partners may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, prospects, financial condition and results of operations could be harmed.

Any product candidates that we may evaluate in clinical studies are subject to certain federal and state healthcare laws and regulations that may affect our business. These laws and regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, as an inducement or reward for their past, current or potential future prescribing, purchase, use, recommending for use, referral, formulary placement, or dispensing of our product candidates;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device research, development, and marketing, prohibits manufacturers from marketing or promoting such products prior to approval; and
- state law equivalents of the above federal laws, such as anti-kickback laws, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In addition, we may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. For example, if we conduct clinical studies in any of the member states of the European Union, the processing of personal data in the European Economic Area, or the EEA, is subject to the 1995 Data Protection Directive, imposing strict obligations and restrictions on the ability to collect, analyze and transfer personal data. In May 2018, the General Data Protection Regulation, or the GDPR, took effect, increasing our obligations with respect to clinical studies conducted in the EEA and increasing the scrutiny applied by clinical study sites located in the EEA to transfers of personal data from such sites to countries that are considered by the European Commission to lack an adequate level of data protection, such as the United States. The compliance obligations

imposed by the GDPR may increase our cost of doing business. In addition, the GDPR imposes substantial fines for breaches of data protection requirements, and it confers a private right of action on data subjects for breaches of data protection requirements.

If our operations are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could impede our ability to operate our business and our financial results. We cannot be certain that compliance programs will address all areas of potential exposure and the risks in this area cannot be entirely eliminated, particularly because the requirements and government interpretations of the requirements in this space are constantly evolving. Any action against us for violation of these laws, rules or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

We face significant competition in an environment of rapid technological and scientific change, and our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may harm our ability, or a licensee's ability, to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

Our future success depends on our ability, or a licensee's ability, to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. In many cases, our product candidates that may be commercialized will compete with existing, market-leading products. The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that are developed or commercialized in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing, and commercialization.

If our product candidates do not obtain regulatory approvals in target indications prior to these or any other competing product candidates, or if our product candidates do not demonstrate superior efficacy, safety or tolerability compared to these and any other approved therapeutics for our target indications, then those product candidates may not be able to compete effectively.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, we or our licensees could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our product candidates infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price that could be charged, for any of our product candidates that may be developed and commercialized. See “—Risks Related to Our Intellectual Property Rights.”

The impact of healthcare reform and other governmental and private payor initiatives, as well as the Inflation Reduction Act of 2022, may harm our business.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, the method of delivery or payment for health care products and services could harm our business, operations and financial condition. There is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in 2010 and in reducing the costs of certain prescription drugs as evidenced by the Inflation Reduction Act of 2022. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: the demand for any drug products for which we may obtain regulatory approval; our ability to set a price that we believe is fair for our product candidates; our ability to obtain coverage and reimbursement approval for a product; our ability to generate revenues and achieve or maintain profitability; and the level of taxes that we are required to pay.

Our future growth may depend, in part, on our, or a licensee's, ability to commercialize any current and potential future product candidates outside the United States, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our or a licensee's ability to commercialize our current and any potential future product candidates outside the United States for which we may rely on partnerships with third parties. If we commercialize our product candidates outside the United States, we would be subject to additional risks and uncertainties, including:

- the customers' ability to obtain reimbursement for our product candidates outside the United States;
- the ability to gain reimbursement in foreign markets at a price that is profitable;
- the inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be harmed by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Our ability to generate meaningful revenues in jurisdictions outside of the United States may be limited due to the strict price controls and reimbursement limitations imposed by governments outside of the United States.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we or our licensees may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, or to meet other criteria for pricing approval. If reimbursement of a product candidate, if approved, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, prospects, financial condition and results of operations could be harmed.

If any of our product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or an ANDA, seeking approval of a generic copy of an approved, small-molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA that references the FDA's prior approval of the small-molecule innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or NDA applicant that seeks to market its product before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents.

Accordingly, if any of our product candidates are approved, competitors could file ANDAs for generic versions of our small-molecule drug products or NDAs that reference our small-molecule drug products, respectively. If there are patents listed for our small-molecule drug products in the Orange Book, those ANDAs and NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we or our licensees may develop or license. Moreover, if any of our patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

Risks Related to Our Business Operations

Our prospects for success depend on our ability to retain Regina Graul, our President and Chief Executive Officer and in the future to attract, retain and motivate qualified personnel.

We are highly dependent on Regina Graul, Ph.D. who is currently our sole employee. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our success also depends on our ability in the future to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we may be able to offer. The failure to succeed in nonclinical

or clinical studies may make it more challenging to recruit and retain qualified personnel. In addition, in order to induce employees to continue their employment with us, we have provided equity awards that vest over time and the value to our employees of such equity awards may be significantly affected by movements in our stock price that are beyond our control and may be at any time insufficient to counteract more lucrative offers from other companies. If we are unable to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of our current and any potential future product candidates in clinical studies and any sale thereof, if approved, exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our product candidates. For example, we may be sued if any such product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things: withdrawal of subjects from our clinical studies; substantial monetary awards to patients or other claimants; decreased demand for our product candidates or any future product candidates following marketing approval, if obtained; damage to our reputation and exposure to adverse publicity; increased FDA warnings on product labels; litigation costs; distraction of management's attention from our primary business; loss of potential revenue; and the inability to successfully commercialize our product candidates or any potential future product candidates, if approved.

We maintain product liability insurance coverage for our clinical studies through both domestic and international insurance policies, subject to an annual coverage limit. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer if a judgment or settlement exceeds available insurance proceeds. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may not be able to obtain this product liability insurance on commercially reasonable terms. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our business, prospects, financial condition and results of operations could be materially harmed.

During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our product candidates, if approved, or require us to suspend or abandon our commercialization efforts of any approved product candidates. Even in a circumstance in which we do not believe that an adverse event is related to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, prospects, financial condition and results of operations.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or The Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the Nasdaq Capital

Market. We are a “smaller reporting company.” For so long as we remain a smaller reporting company, we will be exempt from Section 404(b) of the Sarbanes-Oxley Act, which requires auditor attestation to the effectiveness of internal control over financial reporting. As a smaller reporting company, we are exempt from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on the exemptions available to us as a smaller reporting company. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We are, however, subject to Section 404(a) of the Sarbanes-Oxley Act. Beginning with our annual report on Form 10-K for the fiscal year ended December 31, 2024, we must include a management assessment of the effectiveness of our internal control over financial reporting. As of the expiration of our smaller reporting company status, we will be broadly subject to enhanced reporting and other requirements under the Exchange Act and Sarbanes-Oxley Act. We have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There can be no assurances that in future periods we will be able to timely conclude that our internal control over financial reporting is effective as required by Section 404(a).

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our business, prospects, financial condition and results of operations could be harmed, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Unfavorable global economic and political conditions could harm our business, prospects, financial condition and results of operations.

Our results of operations could be harmed by general conditions in the global economy and in the global financial markets as well as adverse economic conditions caused by political unrest or loss of government funding for product candidates. A severe or prolonged economic downturn and severe political disruption could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business, prospects, financial condition and results of operations.

If our information technology systems or data, or those of CRO and other third parties upon which we rely, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; interruptions to our commercial operations, clinical trials or other operations; harm to our reputation; loss of revenue or profits; loss of sales and other adverse consequences.

In the ordinary course of our business, we and our third-party service providers may process proprietary, confidential, and sensitive data, including personal data (such as health-related data and data related to our clinical trials), intellectual property, and trade secrets (collectively, sensitive information).

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer “hackers,” threat actors, personnel (such as through theft or misuse), “hacktivists”, organized criminal threat actors, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties upon which we rely may be subject to a variety of other evolving threats, including, but not limited to, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence, and other similar threats. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, ability to provide our products, disruption of clinical trials, loss of data (including data related to clinical trials), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws prohibit such payments). Additionally, hybrid and remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely upon third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third parties to provide certain products, including active pharmaceutical ingredients, to operate our business. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if the third parties upon which we rely fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised. We may share or receive sensitive information with or from third parties.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties upon which we rely), but we may not be able to detect, mitigate, and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security

obligations require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data security and public company disclosure obligations may require us to notify relevant stakeholders of certain security incidents, including affected individuals, customers, regulators and investors. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss and other similar harms. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Moreover, experiencing a material cybersecurity incident and any mandatory disclosures could lead to negative publicity, loss of customer, investor or partner confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. In addition, our insurance coverage may not be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Sensitive information of us or our customers could also be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI technologies.

Our employee or future employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable foreign regulators, provide accurate information to the FDA and applicable foreign regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately and/or disclose unauthorized activities to us. In particular, research and development, commercialization and business arrangements in the healthcare industry are subject to considerable laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict, regulate or prohibit a wide range of activities pertaining to clinical trials including the informed consent process, data integrity and conducting the study in accordance with the investigational plan, and for approved products, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have

a significant impact on our business, including the imposition of significant fines or other sanctions, possible exclusions from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages and reputational harm.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and any contract manufacturers and suppliers we engage, are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act, or the FCPA, and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. In some countries in which we operate, the pharmaceutical and life sciences industries are exposed to a high risk of corruption associated with the conduct of clinical trials and other interactions with healthcare professionals and institutions. Any such activities could expose us to potential liability under the FCPA, which may result in us incurring significant criminal and civil penalties and to potential liability under the anti-corruption laws and regulations of other jurisdictions in which we operate. In addition, the costs we may incur in defending against an FCPA investigation could be significant.

Risks Related to Ownership of Our Common Stock

We could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and ability to raise capital.

On June 1, 2022, the Company received a notice from the Nasdaq Stock Market ("Nasdaq") notifying the Company that the closing bid price for the Company's common stock listed on Nasdaq has been below the minimum \$1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a period of 180 calendar days, or until November 28, 2022, to regain compliance with the Bid Price Requirement. The Company did not regain compliance with the Bid Price Requirement by the initial compliance date. On November 29, 2022, however, Nasdaq notified the Company of its eligibility for an additional 180 calendar day period, or until May 29, 2023 (the "Extended Compliance Date"), to regain compliance with the Bid Price Requirement. Nasdaq's determination was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market with the exception of the Bid Price Requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. Effective November 25, 2022, the Company transferred its listing of the Company's common stock from the Nasdaq Global Market to the Nasdaq Capital Market, a continuous trading market that operates in substantially the same manner as the Nasdaq Global Market. The Company's common stock continues to trade under the symbol "CYCN".

We effected a 20:1 reverse stock split in May 2023. As a result, we have regained compliance with the Bid Price Requirement. If the Company does not regain compliance with the Bid Price Requirement in the future, the Company's stock will again be subject to delisting. As a result of amendments in October 2024 to the NASDAQ

delisting procedures, NASDAQ now may automatically delist companies which conduct multiple reverse stock splits in any 12-month period.

The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, including initiating a reverse stock split. However, there can be no assurance that the Company will be able to maintain compliance with the Bid Price Requirement, would receive sufficient shareholder support for a reverse stock split, or will otherwise be in compliance with other Nasdaq Listing Rules.

In January 2026, NASDAQ refiled with the SEC an application to allow NASDAQ to delist certain companies from the NASDAQ Capital Market and NASDAQ Global Market where companies with a market value of listed securities below \$5 million for 30 consecutive business days face immediate suspension and delisting, without the usual compliance period or automatic stay (the “Proposed Market Value Rule”). The SEC has requested comments on the proposed application. The comment period for public comments ended on February 19, 2026, after which time the SEC may elect to accept the NASDAQ proposal. If approved by the SEC, the rule will become effective within 45 days of publication in the Federal Register, or within up to 90 days if extended by the SEC pursuant to Section 19(b)(2) of the Exchange Act. Currently, the Company would not meet the requirements of the Proposed Market Value Rule and if the Proposed Market Value Rule is approved, the Company may not meet the requirements under the Proposed Market Value Rule to maintain its current listing on the NASDAQ Capital Market. The loss of the Company’s listing on the NASDAQ Capital Market would result in the Company’s common stock trading on the OTC Market, which could adversely affect the market price of the Company’s common stock.

The market price of our common stock may fluctuate widely and you could lose all or part of your investment in our common stock as a result.

The market price for our common stock has fluctuated widely, and may in the future fluctuate widely, depending upon many factors, some of which are beyond our control, including the following:

- failure to raise additional capital on a timely basis and the terms on which we raise any capital;
- a relatively low public float for our shares of common stock, which could cause trades of small blocks of shares to have a significant impact on the price of our shares of common stock;
- results and timing of nonclinical studies and clinical studies of our product candidates;
- the commercial performance of our product candidates, those out-licensed to third parties and the Transferred Assets sold to Tisento, if approved, as well as the costs associated with such activities;
- results of clinical studies of our competitors' products;
- failure to adequately protect our trade secrets;
- commencement or termination of any strategic partnership or licensing arrangement;
- regulatory developments with respect to our product candidates or our competitors' products, including any developments, litigation or public concern about the safety of such products;
- announcements concerning product development results, including clinical trial results, the introduction of new products or intellectual property rights of us or others;
- actual or anticipated fluctuations in our financial condition and our quarterly and annual operating results;
- deviations in our operating results from any guidance we may provide or the estimates of securities analysts;
- sufficiency, additions and departures of key personnel;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;

- sales of our common stock by us, our insiders or our other shareholders;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- announcement or expectation of additional financing efforts;
- publication of research reports by securities analysts about us or our competitors or our industry and speculation regarding our company or our stock price in the financial or scientific press or in online investor communities;
- changes in market conditions in the pharmaceutical and biotechnology sector;
- Nasdaq's rules, which impose certain continued listing requirements, including a minimum \$1 bid price, and the Proposed Market Value Rule, such that a failure to meet these requirements would lead Nasdaq to take further steps to delist our common stock; and
- changes in general market and economic conditions.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, financial condition and prospects. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

The market price for our common stock is particularly volatile.

The market for our common stock is characterized by significant price volatility when compared to seasoned issuers, and we expect that our stock price will continue to be more volatile than those of a seasoned issuer. Several factors cause the volatility in our share price. We are a speculative or “risky” investment due to our short operating history, lack of revenues and the uncertain success (including of regulatory approval) of any of our product candidates. As a consequence of this risk, more risk-averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares of our common stock more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Plaintiffs have, in the past, initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of such litigation. Securities litigation could result in substantial costs and liabilities and could divert management’s attention and resources.

We run the risk of inadvertently being deemed an investment company required to register under the Investment Company Act of 1940.

We run the risk of inadvertently being deemed an investment company required to register under the Investment Company Act of 1940 (the “Investment Company Act”) because a significant portion of our assets consists of investments in companies in which we own less than a majority interest. The risk varies depending on events beyond our control, such as significant appreciation or depreciation in the market value of certain of our publicly traded holdings, adverse developments with respect to our ownership of certain of our subsidiaries, transactions involving the sale of certain assets and our participation in any partnership or other fund established to finance future broadband and real estate projects in which we may engage. If we are deemed to be an inadvertent investment company, we may seek to rely on a safe harbor under the Investment Company Act that would provide us a one-year grace period to take steps to avoid being deemed to be an investment company. In order to ensure we avoid being deemed an investment company, we have taken, and may need to continue to take, steps to reduce the percentage of our assets that constitute investment assets under the Investment Company Act. These steps have included, among others, selling marketable securities that we might otherwise hold for the long term and deploying our cash in non-investment assets. We may be forced to sell our investment assets at unattractive prices or to sell assets that we otherwise believe benefit our business in the future to remain below the requisite threshold. We may also seek to acquire additional non-investment assets to maintain compliance with the Investment Company Act, and we may need to incur debt, issue additional equity or enter into other financing arrangements that are not otherwise attractive to our business. Any of these actions could have a material adverse effect on our results of operations and financial condition.

Moreover, we can make no assurance that we would successfully be able to take the necessary steps to avoid being deemed to be an investment company in accordance with the safe harbor. If we were unsuccessful, then we would have to register as an investment company, and we would be unable to operate our business in its current form. We would be subject to extensive, restrictive, and potentially adverse statutory provisions and regulations relating to, among other things, operating methods, management, capital structure, indebtedness, dividends, and transactions with affiliates. If we were deemed to be an investment company and did not register as an investment company when required to do so, there would be a risk, among other material adverse consequences, that we could become subject to monetary penalties or injunctive relief, or both, that we would be unable to enforce contracts with third parties, and/or that third parties could seek to obtain rescission of transactions with us undertaken during the period in which we were an unregistered investment company.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Effective January 1, 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years of research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, in future years we may experience a material decrease in our cash flows from operations and an offsetting similarly sized increase in our net deferred tax assets over these amortization periods. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur and whether we conduct our research and development activities inside or outside the United States and our overall net operating loss position.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income and taxes may be subject to limitations.

Under current law, our federal net operating losses (“NOLs”) generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. As of December 31, 2025, we had federal NOLs of \$211 million. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the

corporation's ability to use its pre-change NOL carryforwards and other pre-change U.S. tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. It is possible that we have experienced an ownership change in the past. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control, as well as the issuance of additional securities if we are successful in raising equity capital.

As a result, our federal NOL carryforwards may be subject to a percentage limitation if used to offset income in tax years following an ownership change. In addition, it is possible that we have in the past undergone, and in the future may undergo, additional ownership changes that could limit our ability to use all of our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which would harm our future operating results by effectively increasing our future tax obligations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceeds the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

If securities or industry analysts fail to initiate or maintain coverage of our stock, publish a negative report or change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our business, our market or our competitors. Currently, no industry analysts cover our stock. If securities or industry analysts fail to initiate coverage of our stock, the lack of exposure to the market could cause our stock price or trading volume to decline. If any of the analysts who cover us or may cover us in the future publish a negative report or change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who covers us or may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We do not expect to pay any cash dividends for the foreseeable future.

We have never paid cash dividends and we do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

We have anti-takeover provisions in our articles of organization and bylaws and are subject to provisions of Massachusetts law that may frustrate any attempt to remove or replace our current board of directors or to effect a change of control or other business combination involving our company.

Our restated articles of organization and bylaws and certain provisions of Massachusetts law may discourage certain types of transactions involving an actual or potential change of control of our company that might be beneficial to us or our security holders. For example, our bylaws grant our directors the right to adjourn any meetings of shareholders. Our board of directors also may issue shares of any class or series of preferred stock in the future without shareholder approval and upon such terms as our board of directors may determine. The rights of the holders of our

common stock will be subject to, and may be harmed by, the rights of the holders of any class or series of preferred stock that may be issued in the future. Massachusetts state law also prohibits us from engaging in specified business combinations unless the combination is approved or consummated in a prescribed manner. These provisions, alone or together, could delay hostile takeovers and changes in control of our company or changes in our management.

Our articles of organization designate the state and federal courts located within the Commonwealth of Massachusetts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers.

Our restated articles of organization designate the state and federal courts located within the Commonwealth of Massachusetts as the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our shareholders, creditors or other constituents, any action asserting a claim arising pursuant to any provision of the Massachusetts Business Corporation Act, or the MBCA, or any action asserting a claim governed by the internal affairs doctrine, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, our articles of organization provide that unless our board of directors consents in writing to the selection of an alternative forum, the U.S. federal district courts shall be the exclusive forum for the resolutions of any complaint asserting a cause of action arising under the U.S. federal securities laws. This exclusive forum provision may limit the ability of our shareholders to bring a claim in a judicial forum that such shareholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against the company and our directors and officers. Alternatively, if a court outside of Massachusetts were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other jurisdictions, which could harm our business, prospects, financial condition and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to patients and clinical trials ("Information Systems and Data").

Our officers and our IT vendors help identify, assess and manage our cybersecurity threats and risks. We manage, identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and risk profile using various methods including, for example: through the use of automated tools, including but not limited to tools for monitoring, geolocation, remote wiping, threat detection, intrusion detection and prevention (including through the use of machine learning, a form of artificial intelligence), patch management, distributed denial of service (DDoS) protection and forensics; conducting (directly or through third parties) regular audits and threat assessments for internal and external threats; subscribing to reports and services that identify cybersecurity threats; analyzing reports of threats and actors; conducting vulnerability assessments to identify vulnerabilities; evaluating our and our industry's risk profile; conducting tabletop incident response exercises; and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident response plans and procedures, disaster recovery/business continuity plans, risk assessments, implementation of security standards and certifications, encryption of data, network security controls, data segregation, access controls, physical security, asset management,

tracking and disposal, systems monitoring, vendor risk management program, employee training and penetration testing.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, cybersecurity risk is addressed as a component of our enterprise risk management program, and members of our management team and IT consultants work together to prioritize our risk management processes, mitigate cybersecurity threats that are more likely to lead to a material impact to our business, and report regularly to our board of directors on cybersecurity matters.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example managed cybersecurity service providers, threat intelligence service providers, dark web monitoring services, and other cybersecurity software providers.

We use third-party service providers to perform a variety of functions throughout our business, including but not limited to application providers, hosting companies, contract manufacturing organizations and contract research organizations. We have a vendor management program to oversee, identify and manage cybersecurity risks associated with our use of these providers. The program includes a risk assessment for vendors that may include, depending on the vendor and nature of services being performed, security questionnaires, review of the vendor's written security program, review of security assessments, audits and reports, vulnerability scans related to the vendor, security assessment calls with the vendor's security personnel, and the imposition of certain contractual obligations on the vendor, among other elements, in accordance with the processes outlined in our internal vendor selection, management, and oversight process policy and other internal guidelines. More specifically, the level of assessment may depend on the following: the nature of the services provided and the data the vendors may collect, retain, and utilize, the sensitivity of the Information Systems and Data at issue, and the identity of the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the risk factor captioned "If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; interruptions to our commercial operations, clinical trials or other operations; harm to our reputation; loss of revenue or profits; loss of sales and other adverse consequences."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. Commencing in 2024, our Audit Committee, on behalf of the board of directors, provides oversight of our cybersecurity risk management program.

Our cybersecurity risk assessment and management processes are implemented and maintained by various members of our management team and IT consultants, which includes individuals who have a diverse combination of relevant expertise, experience, education and training. Our team includes individuals with relevant experience in enterprise risk management and disclosure controls and procedures. Additionally, certain members of our team have experience managing cybersecurity programs and are specifically assigned cybersecurity oversight.

Certain members of our management team are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management. Our cybersecurity incident management team, and other individuals as needed, work to help us mitigate and remediate cybersecurity incidents of which we are notified. In addition, our incident response processes include a procedure for reporting certain cybersecurity incidents to the board of directors.

The board of directors receives regular reports from management concerning our cybersecurity risk management program. The board also receives various summaries and/or presentations related to cybersecurity threats, risks and mitigation.

Item 2. Properties

In April 2021 we completed our exit from our prior laboratory and office facilities in Cambridge Massachusetts and moved to an operating model under which we outsource our research and development laboratory work, and we are currently leasing office space on an “as-needed” basis.

Item 3. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol "CYCN."

Holders of Record

As of February 28, 2026, we had 70 holders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors.

Unregistered Sales of Equity Securities

None.

Purchase of Equity Securities by the Issuer and Affiliated Parties

None.

Item 6. Selected Financial Data.

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

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations included in this Annual Report on Form 10-K.

Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with the audited consolidated financial statements and the corresponding notes included in this 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 Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We focus on building a pipeline of innovative therapeutics to address serious neuropsychiatric disorders with significant unmet medical need. Our current strategic focus is centered on the development of a novel therapeutic approach for neuropsychiatric conditions, with the lead indication being treatment-resistant depression (“TRD”), which we believe represents a substantial clinical and commercial opportunity. Over the past year, we have refined our strategic direction toward programs that combine established pharmacologic agents with enabling technologies designed to improve precision, reproducibility, and patient outcomes. As part of this strategy, Cycleron has evaluated multiple opportunities and prioritized CYC-126, an individualized therapy for TRD as our foundational development program.

In September 2025, we entered into a license agreement with the Massachusetts Institute of Technology (“MIT”) for intellectual property supporting this TRD program. In January 2026, we also entered into a collaboration and option-to-license agreement with Medsteer SAS (“Medsteer”), a developer of anesthesia delivery and monitoring technologies. This agreement provides Cycleron with access to Medsteer’s technical expertise, data assets, and intellectual property relating to technology-enabled drug delivery and physiological monitoring, and grants us the right, but not the obligation, to obtain additional rights under specified conditions. We intend to evaluate these capabilities as part of our broader development strategy for our TRD program. Given the substantial unmet medical need in TRD, the stage of clinical development, and the potential commercial opportunity, we believe this program is well positioned to serve as the foundation of our future development efforts. The program team is currently advancing an integrated clinical, regulatory, and commercial strategy for this TRD program.

In parallel with the advancement of our neuropsychiatric strategy, Cycleron continues to evaluate opportunities related to our legacy soluble guanylate cyclase (“sGC”) stimulator assets, including potential collaborations, monetization opportunities, or other strategic transactions intended to maximize shareholder value.

To support execution of our strategy, we intend to seek additional capital through equity or other financing transactions. In February 2025, our registration statement on Form S-3 (the “Shelf Registration”) was declared effective by the U.S. Securities and Exchange Commission (the “SEC”), providing flexibility to access the capital markets, subject to market conditions and other factors. Under current SEC regulations, because the aggregate market value of our common stock held by non-affiliates is less than \$75 million, the amount of securities we may sell under the Shelf Registration during any twelve-month period is limited to one-third of the aggregate market value of our voting and non-voting common equity held by non-affiliates.

Cycleron operates with a lean organizational structure and utilizes a combination of internal leadership and external consultants to advance our programs while managing operating expenses. Regina Graul, Ph.D., was appointed Chief Executive Officer and Director in August 2024 after previously serving as President. Rhonda Chicko serves as Chief Financial Officer. We may expand our leadership team and operational capabilities over time as our development programs advance.

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 manufacturing, nonclinical studies, clinical trial activities. All research and development expenses are charged to operations as incurred.

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 praliciguat and other related products and forms thereof enumerated in such agreement. In 2021, Akebia paid a \$3.0 million upfront payment to us upon signing of the license agreement.

On December 13, 2024, we announced that Cyclerion and Akebia re-negotiated a mutually beneficial amendment to Akebia's exclusive license agreement for praliciguat. Under this new license amendment, we received \$1.75 million in amendment payments, of which \$1.25 million was paid in December 2024 and an additional payment of \$0.5 million was paid in September 2025. In addition, Akebia is responsible for all intellectual property expenses associated with praliciguat at an earlier date than as originally agreed between the parties. On December 1, 2025, Akebia publicly announced that it has recently initiated Phase 2 clinical trials for the treatment of focal segmental glomerulosclerosis ("FSGS") using Praliciguat. Pursuant to the terms of amendment, upon initiation (defined as first patient dosed) of a Phase 2 clinical trial in the U.S. for a product, a \$1.0 million development milestone payment would be due to us and the payment was received in February 2026. We are eligible to receive additional milestone cash payments of up to approximately \$557.5 million in total related to potential future development, regulatory, and commercialization milestone payments for praliciguat. In exchange for a reduction in certain development milestone payments, we are eligible to receive certain higher-tiered sales-based royalties ranging from mid-single-digits to twenty percent.

In September 2025, we entered in a Material Purchase Agreement (the "Purchase Agreement") with Akebia relating to purchase additional development materials (the "Additional Development Materials") by Akebia for Akebia's use pursuant to the license agreement. Akebia paid \$0.8 million to us for the purchase during the year ended December 31, 2025 and the Additional Development Materials were delivered to Akebia as of December 31, 2025 and we recognized revenue of \$0.8 million during the year ended December 31, 2025.

Oliniciguat is a Phase 2, orally administered, once-daily, vascular sGC stimulator. On July 22, 2024, we entered into an Option to License Agreement (the "Option Agreement") with a third party (the "Optionee"), pursuant to which the Optionee had an option (the "Option") to enter into an exclusive license to oliniciguat for human therapeutics, subject to certain carveouts. Under the terms of the Option Agreement, the Optionee paid us an Option fee of \$150,000 in August 2024 and subsequent fees totaling \$80,000 to extend the term of the Option Agreement. The Optionee originally could exercise the Option on or before March 20, 2025, which option period was ultimately extended through August 22, 2025. Thereafter, the parties had an additional 60 days to negotiate the terms of a definitive license agreement. The parties were unable to agree upon the terms of a license agreement and we were provided notice on October 23, 2025 that it was terminating the Option Agreement. We are currently exploring potential license opportunities for oliniciguat.

Zagociguat and CY3018 are orally administered CNS-penetrant sGC stimulators. On July 28, 2023, Tisento purchased zagociguat and CY3018 in exchange for \$8.0 million in cash consideration, \$2.4 million as reimbursement for certain operating expenses related to zagociguat and CY3018 for the period between signing and closing of the transaction, and 10% of all of Tisento Parent's outstanding equity securities at the time of closing. Research and development expenses decreased significantly after July 28, 2023, due to sale of the Transferred Assets which resulted in a reduction of research and development efforts.

On January 27, 2025, Tisento announced that the first patient had been dosed in its global Phase 2b PRIZM study. The study is investigating the impact of once-daily oral zagociguat treatment on fatigue, cognitive impairment, and other key aspects of the rare mitochondrial disease MELAS (Mitochondrial Encephalomyopathy, Lactic Acidosis,

and Stroke-like Episodes). On June 17, 2025, Tisento announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to zagociguat for the treatment of MELAS.

PRIZM – a Phase 2b Randomized, Placebo-Controlled Trial Investigating Zagociguat in MELAS – is evaluating the efficacy and safety of oral zagociguat 15 mg or 30 mg compared to placebo when administered once-daily for 12 weeks in participants with genetically and phenotypically defined MELAS. The PRIZM study has a crossover design, with two 12-week treatment periods separated by a 4-week washout period. All participants will receive zagociguat during one of the 12-week periods and placebo during the other. Participants who complete the study may be eligible for an open-label extension study. PRIZM is a global study with plans to enroll approximately 44 participants at mitochondrial disease centers of excellence in the U.S., Italy, Germany, United Kingdom, Australia, and Canada. Tisento announced its first patient was dosed in the study in January 2025. In August 2025, Tisento announced that the first patient was enrolled in Tisento's open-label extension study in MELAS and in January 2026, Tisento announced that it completed enrollment in PRIZM. Further information regarding the study is available at ClinicalTrials.gov (NCT06402123).

On September 19, 2025, Cycleron and the Massachusetts Institute of Technology (“MIT”) entered into a Patent License Agreement (the “MIT License Agreement”) pursuant to which MIT granted to us an exclusive worldwide license to develop and commercialize products using certain technology for the treatment of neuropsychiatric disorders, such as depression, in humans. Under the MIT License Agreement, we paid a nominal upfront license fee and patent reimbursement fee. Thereafter, we are also required to pay MIT a nominal annual license maintenance fee. This annual license maintenance fee is nonrefundable; however, the license maintenance fee may be credited to royalties earned during the same calendar year, if any. License maintenance fees paid in excess of royalties due in such calendar year shall not be creditable to amounts due for future years. Under the terms of the MIT License Agreement, MIT will be eligible to receive up to \$4.4 million upon the achievement of certain development, regulatory and sales milestone payments. MIT will also receive tiered royalties in a range of percentages in the low single digits based on future net sales of licensed products as set forth in the MIT License Agreement. Further, we are required to pay MIT varying percentages of income received as consideration for any sublicenses granted pursuant to the MIT License Agreement depending on the circumstances of the sublicense and the development milestones of sublicensed products. The term of the MIT License Agreement will expire in its entirety upon the expiration of certain patent rights for the licensed patents, unless earlier terminated by the parties in accordance with the terms of the MIT License Agreement. We recorded research and development expense of \$0.1 million for the year ended December 31, 2025, which consisted of upfront fees, patent reimbursement fees and transaction costs related to the license.

On January 3, 2026, we and Medsteer SAS (“Medsteer”) entered into a Collaboration and Option Agreement (the “Collaboration Agreement”) pursuant to which Medsteer granted to us (i) a non-exclusive, worldwide, royalty-free, sublicensable license of certain of Medsteer’s technology, software and intellectual property to develop an anesthetic delivery system with Medsteer and (ii) an exclusive option (the “Option”), exercisable at our sole discretion, to obtain an exclusive, worldwide, royalty-bearing, sublicensable license of certain of Medsteer’s technology, software and intellectual property to develop or commercialize licensed products in any field of use except for sedation regulation for patients undergoing major surgery, in multi-bed or intensive unit wards, or in the context of medical transport. We may exercise the Option at any time until the earlier of the second anniversary of the effective date of the Collaboration Agreement, which period may be extended for an additional two years at our option and upon payment of a nominal fee or by mutual agreement of us and Medsteer.

Under the terms of the Collaboration Agreement, the Company will pay to Medsteer a nominal upfront payment, a payment upon exercise of the Option, and Medsteer will be eligible to receive up to \$3.7 million upon the achievement of certain development, regulatory and sales milestone payments. Medsteer will also receive an annual royalty payment and royalties in a percentage in the low single digits based on future net sales of licensed products, subject to certain adjustments as set forth in the Collaboration Agreement.

We continue to evaluate other activities aimed at enhancing shareholder value, which may potentially include collaborations, licenses, mergers, acquisitions, and/or other targeted investments.

The following table summarizes our research and development expenses of continuing operations, employee and facility related costs allocated to research and development expense, and discovery and pre-clinical phase

programs, for the year ended December 31, 2025 and 2024. The product pipeline expenses related primarily to external costs associated with nonclinical studies and clinical trial costs.

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Personnel and related internal costs	\$ 31	\$ 103
Others	928	183
Total research and development expenses	\$ 959	\$ 286

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

The successful development of any current or potential future product candidates is highly uncertain and subject to a number of risks. Please refer to Item 1A, *Risk Factors*, in this Annual Report on Form 10-K.

We are unable to determine the duration and costs to complete current or future nonclinical and clinical stages of any current or potential future product candidates, including as licensed to third parties, or when, or to what extent, we may generate revenues from the commercialization and sale of any current or potential future 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 expenses consist primarily of compensation, benefits and other employee and non-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. 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. generally accepted accounting principles ("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 Annual Report on Form 10-K.

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 Annual Report on Form 10-K.

Results of Operations

The revenue and 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 believe are necessary for an understanding of our consolidated financial statements.

Revenues and Expenses

	Year Ended December 31,		Change	
	2025	2024	\$	%
(dollars in thousands)				
Revenues:				
Revenue from license agreement	\$ 1,000	\$ 1,750	\$ (750)	(43)%
Revenue from purchase agreement	800	—	800	XX
Revenue from option agreement	274	250	24	10%
Total revenues	2,074	2,000	74	4%
Cost and expenses:				
Research and development	959	286	673	235%
General and administrative	6,088	5,342	746	14%
Total cost and expenses	7,047	5,628	1,419	25%
Loss from operations	(4,973)	(3,628)	(1,345)	37%
Other income, net				
Interest income	128	208	(80)	(38)%
Gain from settlement of account payable	—	363	(363)	(100)%
Gain from insurance recovery	1,317	—	1,317	XX
Total other income, net	1,445	571	874	153%
Net loss	\$ (3,528)	\$ (3,057)	\$ (471)	15%

Revenue from license agreement. On December 13, 2024, we entered into the 2024 Amendment with Akebia providing for payments aggregating \$1.75 million all of which was recognized in revenue during the year ended December 31, 2024. \$1.25 million of this amount was paid in December 2024 and the remaining \$0.5 million was paid in September 2025. On December 1, 2025, Akebia publicly announced that it has recently initiated Phase 2 clinical trials for the treatment of focal segmental glomerulosclerosis (“FSGS”) using praliciguat. Pursuant to the terms of amendment, upon initiation of a Phase 2 clinical trial in the U.S. for a product, a \$1.0 million development milestone payment would be due to us. We recognized revenue and accounts receivable of \$1.0 million during the year ended December 31, 2025, and the \$1.0 million payment was received in February 2026.

Revenues from purchase agreement. In September 2025, we entered into the Purchase Agreement with Akebia. Akebia paid \$0.8 million to us for the purchase of Additional Development Materials during the year ended December 31, 2025. The Additional Development Materials were delivered to Akebia as of December 31, 2025 and we recognized revenue of \$0.8 million during the year ended December 31, 2025.

Revenue from option agreement. On July 22, 2024, we entered into the Option Agreement with the Optionee, under which the Optionee had the Option to enter into an exclusive license to olinciguat for human therapeutics, subject to certain carveouts. We recognized revenue of \$0.2 million related to the Option fee payment and expense reimbursement during the year ended December 31, 2024 and we recognized revenue of \$0.3 million related to the Option extension fee, amendment fee and expense reimbursement during the year ended December 31, 2025.

Research and development expenses. The increase in research and development expenses of approximately \$0.7 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 was driven by an increase of \$0.1 million in license fees, \$0.6 million in professional consulting to support the research and

development efforts related to CYC-126, and \$0.1 million in outside service fees, offset by a decrease of \$0.1 million in stock compensation expenses.

General and administrative expenses. The increase in general and administrative expenses of approximately \$0.7 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily driven by an increase of \$0.8 million in professional consulting, \$0.1 million in outside service fee and \$0.7 million in corporate legal fees, offset by a decrease of \$0.3 million in patent fees, \$0.2 million in insurance expense, \$0.1 million in board member fees and \$0.3 million in employee-related expenses.

Interest and other income, net. Interest and other income decreased by approximately \$0.1 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily attributable to the reduction in interest rates.

Gain from settlement of account payable. During the year ended December 31, 2024, we reached a settlement agreement with a vendor for a disputed account payable and recorded a gain of \$0.4 million on settlement of account payable. No such transaction occurred during the year ended December 31, 2025.

Gain from insurance recovery. During the year ended December 31, 2025, we recorded approximately \$1.3 million of insurance recoveries related to loss of advanced intermediated GMP finished materials covered by several policies with third-party insurers. No such gain was recognized during the year ended December 31, 2024.

Liquidity and Capital Resources

To date, we have been funded primarily from sales of our equity securities, payments received in connection with the sale of assets to Tisento, milestone payments from Akebia and an option to license payment.

On March 21, 2025, we closed on a private placement of 499,998 shares of our common stock, pursuant to a Stock Purchase Agreement, for total gross proceeds of approximately \$1.375 million. We also incurred transaction costs of \$0.1 million during the year ended December 31, 2025.

On February 4, 2025, we filed a Registration Statement on Form S-3 (the "2025 Shelf") with the securities and Exchange Commission (the "SEC") in relation to the registration of common stock, preferred stock, warrants and units of any combination thereof for an aggregate initial offering price not to exceed \$25.0 million. The amount we can sell in any twelve-month period under the 2025 Shelf, which was declared effective in February 2025, cannot exceed one-third of the value of our public float.

On May 7, 2025, we entered into an "at the market" equity offering program (the "ATM Program") pursuant to a Sales Agreement (the "2025 Sales Agreement") by and between us and Guggenheim Securities LLC ("Guggenheim Securities"). Pursuant to the terms of the 2025 Sales Agreement, we can sell, from time to time, shares of our common stock, having an aggregate offering price of up to \$20,000,000 from time to time through or to Guggenheim Securities, acting as our agent, subject to the application of General Instruction I.B.6 of Form S-3 ("Instruction I.B.6") pertaining to primary offerings by certain registrants, including shares of common stock offered directly by the Company (the "ATM Shares").

We intend to use the net proceeds from the ATM Program to fund the development of product candidates and for other general corporate purposes, including funding potential new clinical programs and product candidates, financing our existing businesses and operations and expanding our businesses and operations through new product development programs and additional hires.

Subject to the terms and conditions of the Sales Agreement, Guggenheim Securities will use its commercially reasonable efforts to sell the ATM Shares from time to time, based upon our instructions. We have provided Guggenheim Securities with customary indemnification rights, and Guggenheim Securities will be entitled to a commission of 3.0% of the gross proceeds of the ATM Shares sold under the Sales Agreement.

Sales of the ATM Shares will be made pursuant to a previously filed and effective registration statement on Form S-3 (File No. 333-284690). ATM Shares may be offered only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement. Sales of the ATM Shares, if any, will be made at

market prices by any method that is deemed to be an “at the market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Capital Market or any other trading market for our common stock. We have no obligation to sell any of the ATM Shares and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement.

Pursuant to Instruction I.B.6, in no event will we sell ATM Shares with a value exceeding more than one-third of our “public float” (the aggregate market value of our outstanding common stock held by non-affiliates) in any twelve-month period so long as our public float remains below \$75.0 million. During the year ended December 31, 2025, we sold 715,220 ATM Shares for net proceeds of \$2.1 million. On January 6, 2026, we sold 405,000 ATM Shares for net proceeds of \$0.8 million. The Company exhausted all sales under the 2025 Shelf.

The foregoing description of the terms of the Sales Agreement does not purport to be a complete statement of the rights and obligations of the parties under the Sales Agreement and the transactions contemplated thereby and is qualified in its entirety by reference to the Sales Agreement, which is filed as Exhibit 1.1 to the Current Report on Form 8-K as filed with the SEC on May 7, 2025 and is incorporated herein by reference.

On May 19, 2023, we sold 225,000 shares of our common stock, pursuant to a Common Stock Purchase Agreement, and 351,037 shares of Series A Preferred Stock, to our former CEO, for total gross proceeds of approximately \$5 million. There were no material fees or commissions related to the transaction. Such Series A Convertible Preferred Stock is convertible into shares of our common stock on a one-to-one basis. Our shareholders approved such convertibility on July 19, 2023.

On July 28, 2023, we closed the transactions contemplated by the Asset Purchase Agreement receiving proceeds of \$8.0 million as cash consideration, approximately \$2.4 million as reimbursement for certain operating expenses related to zagociguat and CY3018 programs for the period between signing and closing of the transaction, and 10% of all of Tisento Parent’s outstanding equity securities.

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 December 31, 2025, we had approximately \$3.2 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

We evaluated whether there are conditions and events, considered in the aggregate, which raise substantial doubt about our ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of our plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing our analysis, management excluded certain elements of our operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future partnerships, equity or debt issuances, and the potential milestones from the Akebia agreement cannot be considered probable at this time because these plans are not entirely within our control and/or have not been approved by the Board of Directors as of the date of these consolidated financial statements.

We have incurred recurring losses since our inception, including a net loss of 3.5 million for the year ended December 31, 2025. In addition, as of December 31, 2025, we had an accumulated deficit of \$271.0 million. We expect that our cash and cash equivalents as of December 31, 2025, will be sufficient to fund operations through mid-2026, however we will need to obtain additional funding to sustain operations as we expect to continue to generate operating losses for the foreseeable future. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Cash Flows

The following is a summary of cash flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		Change	
	2025	2024	\$	%
	(dollars in thousands)			
Net cash used in operating activities	\$ (3,314)	\$ (4,333)	\$ 1,019	(24)%
Net cash provided by financing activities	\$ 3,322	\$ —	\$ 3,322	—

Cash Flows from Operating Activities

Net cash used in operating activities was \$3.3 million for the year ended December 31, 2025 was primarily a result of our \$3.5 million net loss from operations. The net loss was also adjusted by an increase in accounts receivable of \$0.4 million and a decrease in accrued expenses and other current liabilities of \$0.1 million. The net loss was offset by non-cash stock-based compensation expense of \$0.4 million, an increase of accounts payable of \$0.1 million and an increase of accrued research and development costs of \$0.2 million.

Net cash used in operating activities was \$4.3 million for the year ended December 31, 2024 was primarily a result of our \$3.1 million net loss from operations. The net loss was also adjusted by gain from settlement of accounts payable of \$0.4 million, an increase in accounts receivable of \$0.6 million, a decrease in accounts payable, accrued expenses and other current liabilities of \$1.0 million. The net loss was offset by non-cash stock-based compensation expense of \$0.6 million.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 of \$3.3 million was due to \$1.2 million net proceeds received from the 2025 Equity Private Placement related to the issuance of 499,998 shares of our common stock at a purchase price of \$2.75 per share and \$2.1 million net proceeds received from ATM related to the issuance of 715,220 shares of our common stock under the ATM. There was no financing activity incurred during the year ended December 31, 2024.

Funding Requirements

We expect our expenses to fluctuate as we continue to maintain out-license opportunities and potentially seek to broaden our portfolio through in-licensing of complementary assets. We expect that our cash and cash equivalents as of December 31, 2025, will be sufficient to fund operations through mid-2026. As a result, we will need to obtain additional funding to sustain operations as we expect to continue to generate operating losses for the foreseeable future. Failure to obtain necessary capital when needed may delay development of any current or potential future product candidates, or our ability to continue our operations. Because there is substantial doubt about our ability to continue as a going concern for a reasonable period of time, an investment in our common stock is highly speculative; holders of our common stock could suffer a total loss of their investment.

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 current and any potential future product candidates, and any preclinical studies and clinical trials we may conduct;
- costs, timing and outcome of regulatory review of any current and any potential future product candidates;
- costs of future activities, including medical affairs, manufacturing and distribution, of any current or potential future 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 potential future product candidates, if any.

A change in any of these or other variables with respect to the development of any current or potential future product candidates could significantly change the costs and timing of the development of that product candidate.

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, of which there can be no assurance. 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 and other preferences and rights 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, as to which raise there can be no assurances, we may have to relinquish 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 funds, we may need to cease operations.

Contractual Commitments and Obligations

Tax-related Obligations

We exclude assets, liabilities or obligations pertaining to uncertain tax positions from our contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of December 31, 2025, we had no uncertain tax positions.

Separation Benefits

As part of the separation benefit of the former Chief Financial Officer, we paid \$0.1 million each in May 2024 and August 2024. We have no further separation benefits obligation as of December 31, 2025 and 2024.

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 Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 is set forth in our financial statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and our principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

With respect to the year ended December 31, 2025, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our President and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2025 to provide reasonable assurance that the information required to be disclosed by us in this Annual Report was (a) reported within the time periods specified by SEC rules and regulations and (b) communicated to our management, including our President and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Internal control over financial reporting is a process designed by, or under the supervision of, our President and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Management assessed our internal control over financial reporting as of December 31, 2025, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management’s assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal controls over financial reporting were effective as of December 31, 2025 and provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with GAAP. We reviewed the results of management’s assessment with the Audit Committee of our Board of Directors.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting as we are a “smaller reporting company” and “non-accelerated filer” as defined under the rules of the Securities and Exchange Commission.

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 fiscal year ended December 31, 2025 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. 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. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Our management, including our President and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. 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.

Item 9B. Other Information.

(a) None

(b) Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fourth quarter ended December 31, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

Not applicable.

PART III

We intend to file a definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, or the Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2026 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our Proxy Statement under the captions “Information Regarding the Board of Directors and Corporate Governance,” “Election of Directors,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Proxy Statement under the captions “Executive Compensation” and “Director Compensation” and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans” and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our Proxy Statement under the captions “Transactions with Related Persons” and “Independence of the Board of Directors” and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our Proxy Statement under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See the Index to Consolidated Financial Statements in the Financial Statements Section beginning on page F-1 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted as they are not required, not applicable, or the required information is included in the financial statements or notes to the financial statements.

(a)(3) Exhibits

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Articles of Organization of Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-8 filed on March 29, 2019) (File No. 333-230615))
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated May 15, 2023 (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on May 15, 2023) (File No.001-38787)
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation dated May 19, 2023 (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed on May 25, 2023) (File No. 38787)
3.4	Amended and Restated Bylaws of Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to Registration Statement on Form S-8 filed on March 29, 2019) (File No. 333-230615))
4.1 [#]	Description of Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended
10.1	Intellectual Property License Agreement, dated April 1, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 to Current Report on Form 8-K filed on April 2, 2019 (File No. 001-38787))
10.2 ⁺	Form of Indemnification Agreement between Cycleron Therapeutics, Inc. and individual directors and officers (incorporated by reference to Exhibit 10.7 to Form 10 filed on January 28, 2019 (File No. 001-38787))
10.3 ⁺	Cycleron Therapeutics, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))
10.4 ⁺	Cycleron Therapeutics, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))
10.5 ⁺	Form of Stock Option Agreement under the Cycleron Therapeutics, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to Form 10 filed on March 4, 2019 (File No. 001-38787))
10.6 ⁺	Form of Non-Employee Director Restricted Stock Agreement under the Cycleron Therapeutics, Inc. 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to Form 10 filed on March 4, 2019 (File No. 001-38787))

- 10.7⁺ [Form of Restricted Stock Unit Agreement under the Cycleron Therapeutics, Inc. 2019 Equity Incentive Plan \(incorporated by reference to Exhibit 10.12 to Form 10 filed on March 4, 2019 \(File No. 001-38787\)\)](#)
- 10.8⁺ [Cycleron Therapeutics, Inc. Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan and forms of agreement thereunder \(incorporated by reference to Exhibit 4.5 to Registration Statement on Form S-8 filed on March 29, 2019 \(File No. 333-230615\)\)](#)
- 10.9^{*} [License Agreement, dated as of June 3, 2021, by and between Cycleron Therapeutics, Inc. and Akebia Therapeutics, Inc \(incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed on July 29, 2021 \(File No. 001-38787\)\)](#)
- 10.10^{*} [Amendment #1 to License Agreement by and between the Company and Akebia Therapeutics, Inc. dated December 13, 2024 \(incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on December 17, 2024\)](#)
- 10.11 [Common Stock Purchase Agreement, dated as of June 3, 2021, by and between Cycleron 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 \(File No. 333-257145\)\)](#)
- 10.12^{*} [Patent License Agreement, dated as of September 19, 2025, by and between Cycleron Therapeutics, Inc. and Massachusetts Institute of Technology \(incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed on November 12, 2025 \(File No. 001-38787\)\)](#)
- 10.13⁺ [Amendment to Original Offer Letter to Regina Graul \(incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 7, 2024 \(File No. 001-38787\)\)](#)
- 10.14^{*#} [Collaboration and Option Agreement, dated as of January 3, 2026, by and between Cycleron Therapeutics, Inc. and Medsteer, SAS](#)
- 10.15 [Sales Agreement by and between Cycleron Therapeutics, Inc. and Guggenheim Securities, LLC, dated May 7, 2025 \(incorporated by reference to Exhibit 1.1 to Current Report on Form 8-K filed on May 7, 2025\) \(File No.001-38787\)](#)
- 10.16 [Registration Rights Agreement, dated March 21, 2025, by and among Cycleron Therapeutics, Inc. and the investors party thereto \(incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed on March 25, 2025\) \(File No.001-38787\)](#)
- 10.17⁺ [Consulting Agreement with Rhonda Chicko dated August 4, 2025 \(incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed on August 5, 2025 \(File No. 001-38787\)\)](#)
- 19[#] [Insider Trading Prevention Policy](#)
- 21.1[#] [List of Subsidiaries](#)
- 23.1[#] [Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm](#)
- 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](#)
- 97.1 [Policy for the Recovery of Erroneously Awarded Compensation adopted November 30, 2023 \(incorporated by reference to Exhibit 97.1 to Annual Report on Form 10-K filed on March 4, 2025 \(File No. 001-38787\)\)](#)

101.INS Inline XBRL Instance Document
101.SCH Inline XBRL Taxonomy Extension Schema Document
104 Cover Page Interactive Data File

⁺ Indicates a management contract or compensatory plan.

* 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.

[†] The certifications attached as Exhibits 32.1 and 32.2 that accompany this Report, are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Cycleron Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report irrespective of any general incorporation language contained in such filing.

Filed herewith.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrants have duly caused this report to be signed on their behalf by the undersigned, thereunto duly authorized, on March 30, 2026.

CYCLERION THERAPEUTICS, INC.

By: /s/ Regina Graul

Regina Graul

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Regina Graul and Rhonda Chicko, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Cycleron Therapeutics, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 30, 2026.

<u>Signature</u>	<u>Title</u>
<u>/s/ Regina Graul</u> Regina Graul	President, Chief Executive Officer (Principal Executive Officer) and Director
<u>/s/ Rhonda Chicko</u> Rhonda Chicko	Chief Financial Officer (Principal Financial and Accounting Officer)
<u>/s/ Errol De Souza</u> Errol De Souza	Director
<u>/s/ Peter Hecht</u> Peter Hecht	Director
<u>/s/ Michael Higgins</u> Michael Higgins	Director
<u>/s/ Steven Hyman</u> Steven Hyman	Director
<u>/s/ Dina Katabi</u> Dina Katabi	Director

Index to Consolidated Financial Statements of Cycleron Therapeutics, Inc.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cycleron Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cycleron Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has limited financial resources, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Assessment of indicators of impairment of investment in Tisento Therapeutics Holdings Inc.

Description of the Matter As discussed in Notes 2 and 4 to the consolidated financial statements, as of December 31, 2025, the Company had recognized an Other investment of \$5.4 million which was accounted for as a financial instrument without a readily determinable fair value. Such investment was recorded using the measurement alternative for investments without readily determinable fair values, whereby the investment was measured at cost less any impairment recorded or adjustments for observable price changes. As of December 31, 2025, no impairment loss was recognized.

Auditing the Company's assessment of indicators of impairment of the Other investment was complex and required significant judgment in applying our audit procedures and in the evaluation of the results of the procedures performed to determine if any impairment indicators were present. In addition, there was a significant degree of subjectivity in evaluating the relevance and reliability of the audit evidence obtained.

How We Addressed the Matter in Our Audit We performed audit procedures to test management's evaluation of events or changes in circumstances that might be indicators of impairment of the Company's Other investment. Such procedures included, among others: (i) evaluating the appropriateness of management's assessment of indicators of impairment; (ii) independently obtaining and assessing evidence, including from external sources, to corroborate management's judgments and evaluating contrary evidence; (iii) reading the minutes of the Company's Board of Directors meetings; and (iv) performing inquiries of management of Tisento Therapeutics Holdings Inc. and the Company regarding their knowledge of impairment indicators.

We have served as the Company's auditor since 2018.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 30, 2026

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,240	\$ 3,232
Accounts receivable	1,000	556
Prepaid expenses	384	421
Other current assets	11	16
Total current assets	4,635	4,225
Other investment	5,350	5,350
Total assets	<u>\$ 9,985</u>	<u>\$ 9,575</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 508	\$ 390
Accrued research and development costs	198	52
Accrued expenses and other current liabilities	194	283
Total current liabilities	900	725
Commitments and contingencies (Note 6)	—	—
Stockholders' equity		
Preferred stock, no par value, 100,000,000 shares authorized and 351,037 shares of Series A convertible preferred stock issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, no par value, 400,000,000 shares authorized at December 31, 2025 and 2024; 3,925,314 and 2,710,096 shares issued at December 31, 2025 and 2024, respectively; 3,821,236 and 2,545,922 shares outstanding at December 31, 2025 and 2024, respectively	—	—
Paid-in capital	280,105	276,342
Accumulated deficit	(271,020)	(267,492)
Total stockholders' equity	9,085	8,850
Total liabilities and stockholders' equity	<u>\$ 9,985</u>	<u>\$ 9,575</u>

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

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

	Year Ended December 31,	
	2025	2024
Revenues:		
Revenue from license agreement	\$ 1,000	\$ 1,750
Revenue from purchase agreement	800	—
Revenue from option agreement	274	250
Total revenues	2,074	2,000
Cost and expenses:		
Research and development	959	286
General and administrative	6,088	5,342
Total cost and expenses	7,047	5,628
Loss from operations	(4,973)	(3,628)
Other income, net		
Interest income	128	208
Gain from settlement of account payable	—	363
Gain from insurance recovery	1,317	—
Total other income, net	1,445	571
Net loss	<u>\$ (3,528)</u>	<u>\$ (3,057)</u>
Net loss per share:		
Basic and diluted net loss per share	\$ (1.11)	\$ (1.21)
Weighted average shares used in calculating:		
Basic and diluted shares	3,181	2,518
Other comprehensive loss:		
Net loss	\$ (3,528)	\$ (3,057)
Other comprehensive loss:		
Foreign currency translation adjustment loss	—	(6)
Comprehensive loss	<u>\$ (3,528)</u>	<u>\$ (3,063)</u>

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

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

	Common Stock		Preferred Stock		Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	2,474,159	\$ —	351,037	\$ —	\$ 275,717	\$ (264,417)	\$ (12)	\$ 11,288
Net loss	—	—	—	—	—	(3,057)	—	(3,057)
Vesting of restricted stock awards	71,763	—	—	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and restricted stock awards	—	—	—	—	625	—	—	625
Foreign currency translation adjustment	—	—	—	—	—	—	(6)	(6)
Release of foreign currency translation adjustment upon liquidation of a subsidiary	—	—	—	—	—	(18)	18	—
Balance at December 31, 2024	<u>2,545,922</u>	<u>\$ —</u>	<u>351,037</u>	<u>\$ —</u>	<u>\$ 276,342</u>	<u>\$ (267,492)</u>	<u>\$ —</u>	<u>\$ 8,850</u>
Issuance of common stock - private placement, net of issuance cost	499,998	—	—	—	1,245	—	—	1,245
Issuance of common stock - ATM	715,220	—	—	—	2,077	—	—	2,077
Net loss	—	—	—	—	—	(3,528)	—	(3,528)
Vesting of restricted stock awards	60,096	—	—	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and restricted stock awards	—	—	—	—	441	—	—	441
Balance at December 31, 2025	<u>3,821,236</u>	<u>\$ —</u>	<u>351,037</u>	<u>\$ —</u>	<u>\$ 280,105</u>	<u>\$ (271,020)</u>	<u>\$ —</u>	<u>\$ 9,085</u>

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

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

	Year Ended December 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (3,528)	\$ (3,057)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from settlement of account payable	—	(363)
Share-based compensation expense	441	625
Changes in operating assets and liabilities:		
Accounts receivable	(444)	(556)
Prepaid expenses	37	21
Other current assets	5	(5)
Accounts payable	118	(445)
Accrued research and development costs	146	(38)
Accrued expenses and other current liabilities	(89)	(515)
Net cash used in operating activities	<u>(3,314)</u>	<u>(4,333)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from ATM	2,077	—
Proceeds from private placement	1,375	—
Issuance costs paid for private placement	(130)	—
Net cash provided by financing activities	<u>3,322</u>	<u>—</u>
Effect of exchange rate changes on cash and cash equivalents	—	(6)
Net increase (decrease) in cash and cash equivalents	8	(4,339)
Cash and cash equivalents, beginning of period	3,232	7,571
Cash and cash equivalents, end of period	<u>\$ 3,240</u>	<u>\$ 3,232</u>

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

Cyclerion Therapeutics, Inc.
Notes to the Consolidated Financial Statements

1. Nature of Business

Nature of Operations

Cyclerion Therapeutics, Inc. (“Cyclerion”, the “Company” or “we”) became an independent public company on April 1, 2019 after Ironwood Pharmaceuticals, Inc. completed a tax-free spin-off of their sGC business. Cyclerion has one employee as of December 31, 2025 and also relies on a team of specialist consultants for its operations.

Cyclerion is focused on building a new pipeline of innovative therapeutics to address serious neuropsychiatric diseases. The Company’s current strategic focus is centered on the development of a novel therapeutic approach for treatment-resistant depression (“TRD”), which represents a substantial clinical and commercial opportunity. Over the past year, the Company has refined its strategic direction toward programs that combine established pharmacologic agents with enabling technologies designed to improve precision, reproducibility, and patient outcomes. As part of this strategy, Cyclerion has evaluated multiple opportunities and prioritized CYC-126, an individualized therapy for TRD as its foundational development program. In September 2025, the Company entered into a license agreement with the Massachusetts Institute of Technology (“MIT”) for intellectual property supporting this program (see Note 11), and in January 2026 entered into a collaboration and option-to-license agreement with Medsteer SAS (“Medsteer”) to access certain technology, data assets, and technical know-how related to drug delivery and physiological monitoring. The Company is advancing development planning, regulatory strategy, and commercial positioning for this program and intends to initiate a Phase 2 proof-of-concept study in Australia in the second half of 2026.

In parallel with the advancement of its neuropsychiatric strategy, Cyclerion continues to evaluate opportunities related to its legacy soluble guanylate cyclase (“sGC”) stimulator assets, including potential collaborations, monetization opportunities, or other strategic transactions designed to maximize shareholder value.

Praliciguat is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, Cyclerion 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 praliciguat and other related products and forms thereof enumerated in such agreement. In 2021, Akebia paid a \$3.0 million upfront payment to the Company upon signing of the license agreement.

On December 13, 2024, Cyclerion announced that Cyclerion and Akebia have re-negotiated a mutually beneficial amendment to their exclusive license agreement for praliciguat, a systemic sGC stimulator. Under this new license amendment, Cyclerion will receive \$1.75 million in amendment payments, of which \$1.25 million was paid in December 2024 and an additional payment of \$0.5 million was received in September 2025. In addition, Akebia is responsible for all intellectual property expenses associated with praliciguat. On December 1, 2025, Akebia publicly announced that it has recently initiated (defined as first patient dosed) Phase 2 clinical trials for the treatment of focal segmental glomerulosclerosis (“FSGS”) using praliciguat. Pursuant to the terms of amendment, upon initiation of a Phase 2 clinical trial in the U.S. for a product, a \$1.0 million development milestone payment would be due to us and it was received in February 2026. The Company is eligible to receive additional milestone cash payments of up to approximately \$557.5 million in total potential future development, regulatory, and commercialization milestone payments for praliciguat. In exchange for a reduction in certain development milestone payments, Cyclerion is eligible to receive certain higher-tiered sales-based royalties ranging from mid-single-digits to twenty percent.

Oliniciguat is a Phase 2, orally administered, once-daily, vascular sGC stimulator. On July 22, 2024, the Company entered into an Option to License Agreement (the “Option Agreement”) with a third party (the “Optionee”), pursuant to which the Optionee had an option (the “Option”) to enter into an exclusive license to oliniciguat for human therapeutics, subject to certain carveouts. Under the terms of the Option Agreement, the Optionee paid the Company an Option fee of \$150,000 in August 2024 and subsequent fees totaling \$80,000 to

extend the term of the Option Agreement. The Optionee originally could exercise the Option on or before March 20, 2025, which was ultimately extended through August 22, 2025. Thereafter, the parties had an additional 60 days to negotiate the terms of a definitive license agreement. The parties were unable to agree upon the terms of a license agreement and the Company provided notice on October 23, 2025 that it was terminating the Option Agreement. The Company is currently exploring potential license opportunities for olinciguat.

Zagociguat is a clinical-stage CNS-penetrant sGC stimulator that has shown rapid improvement in cerebral blood flow, functional brain connectivity, brain response to visual stimulus, cognitive performance, and biomarkers associated mitochondrial function and inflammation in clinical studies. CY3018 is a CNS-targeted sGC stimulator that preferentially localizes to the brain and has a pharmacology profile that suggests its potential for the treatment of neuropsychiatric diseases and disorders. On July 28, 2023, the Company sold Zagociguat and CY3018 to Tisento Therapeutics, Inc. (“Tisento”), a newly formed private company focused on their development, in exchange for \$8.0 million in cash consideration, \$2.4 million as reimbursement for certain operating expenses related to zagociguat and CY3018 for the period between signing and closing of the transaction, and 10% of all of Tisento’s parent’s outstanding equity securities (“Tisento Parent”).

Cyclerion GmbH, a wholly owned subsidiary, was incorporated in Zug, Switzerland on May 3, 2019. The functional currency is the Swiss franc. Cyclerion GmbH was liquidated and de-registered in May 2024.

Cyclerion Securities Corporation, a wholly owned subsidiary, was incorporated in Massachusetts on November 15, 2019 and was granted securities corporation status in Massachusetts.

Stock Purchase Agreement

In March 2023, the Company entered into a stock purchase agreement with the Company's former Chief Executive Officer (the “CEO”) pursuant to which he invested \$5 million in cash for 225,000 shares of common stock and 351,037 shares of Series A Convertible Preferred Stock of the Company at a price of \$8.68 per share (after giving effect to the 1-for-20 reverse stock split the Company implemented on May 15, 2023). The Series A Convertible Preferred Stock is convertible into shares of the Company's common stock on a one-to-one basis. The closing of the equity investment took place on May 19, 2023, and (to comply with Nasdaq listing requirements) the Company's shareholders approved such convertibility on July 19, 2023.

2025 Equity Private Placement

On March 21, 2025, the Company entered into a Stock Purchase Agreement (the “2025 Equity Private Placement”) for a private placement of 499,998 shares of the Company’s common stock, at a purchase price of \$2.75 per share for total gross proceeds of approximately \$1.375 million. The closing of the 2025 Equity Private Placement occurred on March 25, 2025. The Company incurred transaction costs of \$0.1 million for the 2025 Equity Private Placement. The Shares issued were not registered under the Securities Act of 1933, as amended, or any state securities laws and will be issued pursuant to the exemption from registration provided for under Section 4(a)(2) of the Securities Act as a transaction not involving a public offering.

In connection with the 2025 Equity Private Placement, the Company entered into a Registration Rights Agreement with the investors, dated March 21, 2025, pursuant to which the Company agreed to register the resale of the Shares pursuant to a registration statement which was filed with the SEC and declared effective by the SEC on May 15, 2025.

At-the-Market Offering

On February 4, 2025, 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, warrants and units of any combination thereof for an aggregate initial offering price not to exceed \$25.0 million. The Registration Statement was declared effective by the SEC in February 2025.

On May 7, 2025, the Company and Guggenheim Securities, LLC (“Guggenheim Securities”) entered into a Sales Agreement (the “Sales Agreement”), pursuant to which the Company may offer and sell shares of common stock, no par value per share (the “Shares”), having an aggregate offering price of up to \$20,000,000 from time to

time through or to Guggenheim Securities, acting as the Company's agent, subject to the application of General Instruction I.B.6 of Form S-3 ("Instruction I.B.6") pertaining to primary offerings by certain registrants, including the Company. The Company has provided Guggenheim Securities with customary indemnification rights, and the Company will pay Guggenheim Securities cash commission of 3.0% of the gross proceeds of the Shares sold under the Sales Agreement.

During the year ended December 31, 2025, the Company sold 715,220 shares of its common stock for net proceeds of \$2.1 million under the Sales Agreement, after deducting commissions paid to Guggenheim Securities of \$0.1 million.

Basis of Presentation

The consolidated financial statements and the related disclosures have been prepared in accordance with U.S. generally accepted accounting principles. In the opinion of management, the 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 fiscal years presented.

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries, Cyclerion Securities Corporation and Cyclerion GmbH which was dissolved in May 2024. All significant intercompany accounts and transactions have been eliminated in the preparation of the accompanying consolidated financial statements.

Going Concern

At each reporting period, in accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, 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.

This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future partnerships, equity or debt issuances, certain cost reduction measures and the potential milestones from the Akebia agreement cannot be considered probable at this time because these plans are not entirely within the Company's control and/or have not been approved by the Board of Directors as of the date of these consolidated financial statements.

The Company expects that its cash and cash equivalents as of December 31, 2025, will be sufficient to fund operations through mid-2026, however the Company will need to obtain additional funding to sustain operations as it expects to continue to generate operating losses for the foreseeable future. The Company's expectation to generate negative operating cash flows in the future and the need for additional funding to support its planned operations, raise substantial doubt regarding the Company's ability to continue as a going concern. Management's plans to alleviate the conditions that raise substantial doubt include reduced spending, and the pursuit of additional capital. Management has concluded the likelihood that its plan to successfully obtain sufficient funding, or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and

satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

2. Summary of Significant Accounting Policies

Segment Information

The Company operates and manages its business as a single segment for the purposes of assessing performance and making operating decisions. The Company's president and chief executive officer, who is the chief operating decision maker ("CODM"), reviews the Company's financial information on a consolidated basis for purposes of evaluating financial performance and allocating resources. When evaluating the Company's financial performance, the CODM regularly reviews net loss, non-operating expenses and operating expenses excluding non-cash stock based compensation expense.

Variable Interest Entities

The Company reviews each legal entity in which it has a financial interest to determine whether or not the entity is a variable interest entity or VIE. If the entity is a VIE, the Company assesses whether or not it is the primary beneficiary of that VIE based on a number of factors, including (i) which party has the power to direct the activities that most significantly affect the VIE's economic performance, (ii) the parties' contractual rights and responsibilities pursuant to any contractual agreements and (iii) which party has the obligation to absorb losses or the right to receive benefits from the VIE. If the Company determines that it is the primary beneficiary of a VIE, it consolidates the financial statements of the VIE into its consolidated financial statements at the time that determination is made. On a quarterly basis, the Company evaluates whether it continues to be the primary beneficiary of any consolidated VIEs. If the Company determines that it is no longer the primary beneficiary of a consolidated VIE, or no longer has a variable interest in the VIE, the Company deconsolidates the VIE in the period that the determination is made.

Investment

The Company accounts for investments in equity securities without a readily determinable fair value at cost, minus impairment. If the Company identifies observable price changes in orderly transactions for an identical or a similar investment of the same issuer, the Company will measure the equity security at fair value as of the date that the observable transaction occurred in accordance with ASC Topic 321, Investments-Equity Securities.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles ("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, fair value determination of other investment, 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.

Cash and Cash Equivalents

The Company considers all highly liquid investment instruments with a remaining maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents may consist of

money market funds and overnight repurchase agreements. The carrying amount of cash equivalents approximates fair value.

Fair Value of Investment Instruments

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

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

Foreign Currency Translation Adjustment

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

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

Accounts Receivable

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices. The Company believes that credit risks associated with these agreements are not significant. To date, the Company has not had significant write-offs of bad debt and the Company did not have an allowance for doubtful accounts as of December 31, 2025 or 2024.

Revenue

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

success. The Company derives revenue from (1) license agreement, (2) purchase agreement and (3) option to license agreement which are fully described in Note 11, *License and Option Agreement*.

Research and Development Costs

The Company expenses research and development costs to operations as incurred. The Company defers and capitalizes nonrefundable advance payments made by the Company for research and development activities until the related goods are received or the related services are performed. The Company estimates the period over which such services will be performed and the level of effort to be expended in each period. If actual timing of performance or the level of effort varies from the estimate, the Company will adjust the amounts recorded accordingly. The Company has not experienced any material differences between accrued or prepaid costs and actual costs since inception.

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

General and Administrative Expenses

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

Income taxes

The Company is primarily subject to U.S. Federal and Massachusetts state income taxes. For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are realizable.

The tax positions taken or expected to be taken in the course of preparing the Company tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. It does not consider the likelihood of whether or not the IRS will review the position. Cyclerion evaluates uncertain tax positions on a quarterly basis and adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any changes to these estimates, based on the actual results obtained and/or a change in assumptions, could affect Cyclerion's income tax provision in future periods. There were no uncertain tax positions that require accrual or disclosure in the consolidated financial statements as of December 31, 2025, and 2024. The Company's policy is to recognize interest and penalties related to income tax, if any, in income tax expense. As of December 31, 2025 and 2024, the Company has no accruals for interest or penalties related to income tax matters.

Patent Costs

Patent fees and patent related costs in connection with filing and prosecuting patent applications are expensed as incurred and are classified as general and administrative expenses in the accompanying consolidated financial statements. The Company incurred and recorded as operating expense legal and other fees related to patents of approximately \$0.3 million and \$0.6 million for the years ended December 31, 2025 and 2024, respectively.

Interest and Other Income, Net

For the year ended December 31, 2025 and 2024, interest and other income, net consisted of a \$0.1 million and \$0.2 million of interest income related to interest generated from the Company's cash and cash equivalents balances, respectively.

Subsequent Events

The Company considers events or transactions that have occurred after the balance sheet date of December 31, 2025, but prior to the filing of the financial statements with the Securities and Exchange Commission, to provide additional evidence relative to certain estimates or to identify matters that require additional recognition or disclosure. Subsequent events have been evaluated through the filing of the financial statements accompanying this Annual Report on Form 10-K. See Note 12, *Subsequent Events*.

Recently Issued 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 years ended December 31, 2025 and 2024, that had a material effect on its consolidated financial statements.

In August 2025, the FASB issued ASU No. 2025-05, Financial Instruments—Credit Losses (Topic 326), which requires incremental disclosures on estimating expected credit losses. The Company will adopt this guidance beginning with its annual report for fiscal 2027. The Company is currently evaluating the potential effect that the updated standard will have on its financial statement disclosures.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures (Topic 280), which requires incremental disclosures on reportable segments, primarily through enhanced disclosures on significant segment expenses. The Company adopted this guidance beginning with its annual report for fiscal 2025 and interim periods thereafter on a retrospective basis. The adoption did not have a material effect on the consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which focuses on the rate reconciliation and income taxes paid. ASU No. 2023-09 requires a public business entity (PBE) to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. For PBEs, the new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than PBEs, the requirements will be effective for annual periods beginning after December 15, 2025. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all period presented. As of December 31,

2025, the Company adopted this new ASU and it only impacts the Company's income tax disclosures with no impact to its operations, cash flows, or financial condition.

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. 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 December 31, 2025 and December 31, 2024 (in thousands):

	Fair Value Measurements as of December 31, 2025:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 3,072	\$ —	\$ —	\$ 3,072
Cash equivalents	<u>\$ 3,072</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,072</u>
	Fair Value Measurements as of December 31, 2024:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 3,025	\$ —	\$ —	\$ 3,025
Cash equivalents	<u>\$ 3,025</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,025</u>

During the year ended December 31, 2025 and 2024, 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 accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of these amounts.

4. Other Investment

On July 28, 2023, the Company closed the transactions contemplated by the Asset Purchase Agreement receiving proceeds of \$8.0 million as cash consideration, approximately \$2.4 million as reimbursement for certain operating expenses related to zagociguat and CY3018 programs for the period between signing and closing of the transaction, and 10% of all of Tisento Parent's outstanding equity securities which fair value was determined to be \$5.3 million at the time of closing. The Company's investment in Tisento Parent does not provide it with significant influence over Tisento Parent.

The Company has determined that the Company's investment in Tisento Parent is an equity security, whereby such investment does not give the Company a controlling financial interest or significant influence over the investee. Further, the Company assessed the accounting for its investment in Tisento Parent in accordance with ASC 810-10, Consolidation—Overall. After determining that no scope exception applies under the guidance of ASC 810-10-15-12 and ASC 810-10-15-17, the Company concluded that it has a variable interest in Tisento Parent through its investment in Tisento Parent common stock. Tisento Parent does not have sufficient equity to finance its activities without additional subordinated financial support as Tisento Parent is a startup entity in its early stages of raising funds and will require significant capital to advance its programs to commercial stage. Therefore, the Company concluded that its investment in Tisento Parent is a variable interest entity ("VIE") in accordance with ASC 810-10-15-14(a) and is subject to potential consolidation under the VIE model. However, all activities that most significantly impact Tisento Parent and its subsidiary's economic performance are directed by the Tisento Parent board and the board approves decisions by a simple majority. Based on the board composition, the Company

determined that no one party has control over the Tisento Parent board and power is not shared because the activities that most significantly affect Tisento Parent and its subsidiary's economic performance do not require the consent of all of the parties. Rather, all decisions are made by a simple majority vote of the Tisento Parent board. Therefore, because the Company controls no director of Tisento Parent, the Company cannot unilaterally direct any of the activities that most significantly impact Tisento Parent and its subsidiary's economic performance. Accordingly, the Company does not hold a controlling financial interest in Tisento Parent. Because both criteria (a) and (b) above have to be met for the application of the guidance in ASC 810-10-25-44B and criteria (a) has not been met, The Company concluded that it should not consolidate Tisento under the VIE model.

Accordingly, the Company has accounted for the investment as a financial instrument without a readily determinable fair value. Such investment is recorded using the measurement alternative for investments without readily determinable fair values, whereby the investment is measured at cost less any impairment recorded or adjustments for observable price changes. An impairment loss is recognized in the consolidated statements of operations and comprehensive loss equal to the amount by which the carrying value exceeds the fair value of the investment. As of December 31, 2025, no impairment loss was recognized. The Company considers the cost of the investment to be the maximum exposure to loss as a result of its involvement with the non-affiliated entity.

The initial fair value of the investment in Tisento Parent was determined by reference to the risk-adjusted net assets value using the discounted cash flow method. The estimated net assets value of Tisento Parent includes the cash generated/used from the operations and the proceeds from equity financing. Valuations were derived by reference to observable valuation measures for comparable companies or transactions, including weighted average cost of capital (21% to 23%), terminal decline rate (25% to 75%) and the discount rate referenced by a two-year treasury rate of 4.01%.

5. Accrued Expenses and Other Current Liabilities

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

	December 31, 2025	December 31, 2024
Professional fees	\$ 143	\$ 220
Employee compensation	13	33
Other	38	30
Accrued expenses and other current liabilities	<u>\$ 194</u>	<u>\$ 283</u>

6. Commitments and Contingencies

Other Funding Commitments

The Company may enter 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, Cycleron 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 December 31, 2025 or December 31, 2024.

Separation Benefits

As part of the separation benefit of the former Chief Financial Officer, the Company paid \$0.1 million each in May 2024 and August 2024. The Company has no further separation benefits obligation as of December 31, 2025 and 2024.

7. Share-based Compensation Plans

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

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

The following table provides share-based compensation reflected in the Company’s consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	\$ 29	\$ 91
General and administrative	412	534
	<u>\$ 441</u>	<u>\$ 625</u>

Stock Options

Stock options granted under the Company’s equity plans generally have a ten-year term and vest over a period of four years, provided the individual continues to serve at the Company through the vesting dates. Options granted under all equity plans are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. The estimated fair value of options, including the effect of estimated forfeitures, is recognized over the requisite service period, which is typically the vesting period of each option.

A summary of stock option activity for the year ended December 31, 2025 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, 2024	335,448	\$ 158.98	4.7	\$ —
Granted	25,000	\$ 2.36		
Exercised	—	\$ —		
Cancelled or forfeited	(62,686)	\$ 140.44		
Outstanding as of December 31, 2025	<u>297,762</u>	<u>\$ 149.73</u>	<u>4.9</u>	<u>\$ —</u>
Exercisable at December 31, 2025	<u>232,385</u>	<u>\$ 187.20</u>	<u>4.0</u>	<u>\$ —</u>

During the years ended December 31, 2025 and 2024, the Company granted stock options to purchase an aggregate of 25,000 shares and 55,849 shares, respectively, at weighted average grant date fair values per option share of \$2.14 and \$2.80 respectively.

There were no options exercised during the year ended December 31, 2025 and 2024.

As of December 31, 2025, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested time-based stock options held by the Company's employee and non-employees is \$0.1 million and the weighted average period over which that expense is expected to be recognized is 3.03 years.

The weighted-average Black-Scholes assumptions used in estimating the fair value of the stock options granted by Cycleron during the years ended December 31, 2025 and 2024 were as follows:

	Year ended December 31,	
	2025	2024
Weighted average risk-free interest rate	3.79%	3.64%
Expected dividend yield	—	—
Expected option term (in years)	5.4	6.0
Expected stock price volatility	141.07%	111.97%

For the years ended December 31, 2025 and 2024, expected volatility was estimated using an average of the historical volatility of the common stock of a group of similar companies that were publicly traded. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

The Company has granted certain employees performance-based options to purchase shares of common stock. These options are subject to performance-based milestone vesting. During the year ended December 31, 2025 and 2024, there were no shares that vested as a result of performance milestone achievements. No share-based compensation expense related to these performance-based options was recognized during the years ended December 31, 2025, and 2024, respectively.

Restricted Stock Awards

No RSA was granted during the year ended December 31, 2025. The Company granted 65,000 RSAs during the year ended December 31, 2024. The fair value of all RSAs is based on the market value of the Company's common stock on the date of grant. Compensation expense, including the effect of estimated forfeitures, is recognized over the applicable service period.

A summary of RSA activity for the years ended December 31, 2025 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	164,174	\$ 2.56
Granted	—	—
Vested	(60,096)	2.52
Forfeited	—	—
Unvested as of December 31, 2025	<u>104,078</u>	<u>\$ 2.57</u>

As of December 31, 2025, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested RSAs held by the Company's directors is \$0.2 million and the weighted average period over which that expense is expected to be recognized is 1.69 years.

8. 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:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss (in thousands)	\$ (3,528)	\$ (3,057)
Denominator:		
Weighted average shares used in calculating net loss per share — basic and diluted (in thousands)	3,181	2,518
Net loss per share — basic and diluted	<u>\$ (1.11)</u>	<u>\$ (1.21)</u>

The Company excludes potential shares of common stock related to Preferred Stock, stock options and RSAs from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive. The following table sets forth potential shares that were considered anti-dilutive for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Preferred Stock	351,037	351,037
Stock Options	297,762	335,448
RSAs	104,078	164,174
	<u>752,877</u>	<u>850,659</u>

9. Income Taxes

The components of net income (loss) before income tax expense are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Domestic	\$ (3,528)	\$ (3,061)
Foreign	—	3
Total	\$ (3,528)	\$ (3,058)

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows after adoption of ASU 2023-09 on a retrospective basis (in thousands):

	Year Ended December 31,			
	2025		2024	
	Amount	Percent	Amount	Percent
Pretax loss	\$ (3,528)		\$ (3,058)	
US Federal Statutory Tax Rate	(741)	21.0%	(642)	21.0%
Foreign tax effects	—	—	(1)	0.0%
Non-deductible items	571	-16.2%	88	-2.9%
Tax credits	—	—	(11)	0.4%
Change in valuation allowance	170	-4.8%	566	-18.5%
	\$ —	0.0%	\$ —	0.0%

The Company's effective tax rate differs from the statutory rate primarily due to continued losses and the maintenance of a full valuation allowance on deferred tax assets, resulting in zero income tax expense for the period.

Deferred tax assets (liabilities) consist of the following as of December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	\$ 57,618	\$ 53,281
Tax credit carryforwards	10,385	10,383
Share-based compensation	6,500	7,122
Capitalized research and development	8,867	12,370
Intangibles	20	—
Total deferred tax assets	\$ 83,390	\$ 83,156
Valuation allowance	(83,390)	(83,156)
Net deferred tax assets	\$ —	\$ —

The Company has evaluated the positive and negative evidence bearing upon the possible realization of its deferred tax assets. Management has considered the Company's history of operating losses, in addition to the expected timing of the reversal of existing temporary differences and concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company will not realize the benefit of its deferred tax assets. Accordingly, the net deferred tax assets have been fully reserved at December 31, 2025 and December 31, 2024. Management reevaluates the positive and negative evidence on a quarterly basis.

The valuation allowance increased by approximately \$0.2 million during the year ended December 31, 2025 primarily due to increases in capitalized research and development expenses, net operating losses, tax credit carryforwards and deferred tax assets related to share-based compensation.

At December 31, 2025 and 2024, Cycleron has federal net operating loss carryforwards of approximately \$211 million and \$195 million, respectively, to offset future federal taxable income that will be carried forward indefinitely until utilized. As of December 31, 2025 and 2024, Cycleron had state net operating loss carryforwards of approximately \$212 million and \$196 million, respectively, to offset future state taxable income, which will begin

to expire in 2039 and will continue to expire through 2045. Cycleron also had tax credit carryforwards of approximately \$10.8 million as of December 31, 2025, to offset future federal and state income taxes. Federal credits begin to expire in 2039 and will continue to expire through 2044. State credits begin to expire in 2034 and continue through 2039.

The Company's ability to use its operating loss carryforwards and tax credits to offset future taxable income could be subject to restrictions under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"). These potential restrictions may limit the future use of the operating loss carryforwards and tax credits if certain ownership changes described in the Internal Revenue Code occur. Changes in stock ownership may occur that would create these limitations on the Company's use of the operating loss carryforwards and tax credits. In such a situation, the Company may be required to pay income taxes, even though significant operating loss carryforwards and tax credits exist.

The Company has not as yet conducted a study of its research and development credit carry forwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheets or statements of operations if an adjustment were required.

Upon audit, taxing authorities may challenge all or part of an uncertain income tax position. While Cycleron has no history of tax audits since its inception on a standalone basis, it may be subject to tax audits by federal and state taxing authorities in the future. Accordingly, Cycleron regularly assesses the outcome of potential examinations in each of the taxing jurisdictions when determining the adequacy of the amount of unrecognized tax benefit recorded. Cycleron had no unrecognized tax benefits as of December 31, 2025 and 2024. Cycleron will recognize interest and penalties, if any, related to uncertain tax positions in income tax expense. As of December 31, 2025 and 2024, no interest or penalties have been accrued. There are no current federal or state income tax audits in progress.

10. Defined Contribution Plan

The Company has established a defined contribution 401(k) Savings Plan which allows eligible employees to contribute from 1% to 100% of their compensation, subject to certain IRS limits. The Company's contributions to the plan are at the sole discretion of the board of directors. Currently, the Company provides a matching contribution of 75% of the employee's contributions, up to \$6,000 annually.

Included in compensation expense is de minimis related to the defined contribution 401(k) Savings Plan for the years ended December 31, 2025 and 2024, respectively.

11. License and Option Agreement

Patent License Agreement

On September 19, 2025, the Company and MIT entered into a Patent License Agreement (the "MIT License Agreement") pursuant to which MIT granted to the Company an exclusive worldwide license to develop and commercialize products using certain technology for the treatment of neuropsychiatric disorders, such as depression, in humans. Under the MIT License Agreement, the Company paid a nominal upfront license fee and patent reimbursement fee. Thereafter, the Company is also required to pay MIT a nominal annual license maintenance fee. This annual license maintenance fee is nonrefundable; however, the license maintenance fee may be credited to royalties earned during the same calendar year, if any. License maintenance fees paid in excess of royalties due in such calendar year shall not be creditable to amounts due for future years. Under the terms of the MIT License Agreement, MIT will be eligible to receive up to \$4.4 million upon the achievement of certain development, regulatory and sales milestone payments. MIT will also receive tiered royalties in a range of percentages in the low single digits based on future net sales of licensed products as set forth in the MIT License Agreement. Further, the Company is required to pay MIT varying percentages of income received as consideration for any sublicenses granted pursuant to the MIT License Agreement depending on the circumstances of the

sublicense and the development milestones of sublicensed products. The term of the MIT License Agreement will expire in its entirety upon the expiration of certain patent rights for the licensed patents, unless earlier terminated by the parties in accordance with the terms of the MIT License Agreement.

The Company recorded research and development expense of \$0.1 million for the year ended December 31, 2025, which consisted of upfront fees, patent reimbursement fees and transaction costs related to the license.

Akebia License Agreement

On June 3, 2021, the Company and Akebia entered into a License Agreement (the "Akebia License Agreement") relating to the exclusive worldwide license by the Company to Akebia of its rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing the pharmaceutical compound known as pralicipuat and other related products and forms thereof enumerated in the License Agreement (collectively, the "Products"). Pursuant to the Akebia 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. On December 13, 2024, the Company and Akebia entered into Amendment #1 to the License Agreement (the "2024 Amendment") to the original License Agreement between the parties dated June 3, 2021.

Under the terms of the 2024 Amendment, Akebia paid \$1.75 million in amendment payments, of which \$1.25 million was paid in December 2024 and an additional payment of \$0.5 million was paid in September 2025. In addition, Akebia has agreed to assume control of the preparation, filing, prosecution and maintenance of certain Cycleron patents, and the expenses associated therewith, at an earlier date than as originally agreed between the parties. The parties have agreed to the reduction of certain development milestones and the increase of certain royalty rates on net sales and sublicense income. On December 1, 2025, Akebia publicly announced that it has recently initiated Phase 2 clinical trials for the treatment of focal segmental glomerulosclerosis ("FSGS") using pralicipuat. Pursuant to the terms of amendment, upon initiation of a Phase 2 clinical trial in the U.S. for a product, a \$1.0 million development milestone payment would be due to the Company and which was received in February 2026. Pursuant to the terms of the Akebia License Agreement, as amended, Cycleron is eligible to receive additional potential future development, regulatory, and commercialization milestone payments up to \$557.5 million in total, and Akebia will pay Cycleron tiered royalties ranging from mid-single digit to twenty percent of net sales. Cycleron's obligations to deliver certain drug products have also ceased.

Pursuant to the Akebia License Agreement, the Company determined the Akebia License Agreement represents a service arrangement under the scope of ASC 606. Given the reversion of the rights under the Akebia 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 its 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 the Company.

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.

Akebia Material Purchase Agreement

On September 3, 2025, the Company and Akebia entered into a Material Purchase Agreement (the "Purchase Agreement") relating to the purchase of additional development materials (the "Additional Development Materials") by Akebia for Akebia's use pursuant to the Akebia License Agreement. Akebia paid \$0.8 million to the Company for the purchase during the year ended December 31, 2025 and the Additional Development Materials

were delivered to Akebia as of December 31, 2025.

The Company determined the Purchase Agreement has stand-alone value under the scope of ASC 606 and should not be combined with the Akebia License Agreement or the Amendment. The delivery of the Additional Development Materials by the Company represents a single performance obligation and consideration was recognized upon delivery. The Company recognized revenue of \$0.8 million during the year ended December 31, 2025.

Option Agreement

On July 22, 2024, the Company entered into an Option to License Agreement (the “Option Agreement”) with a third party (the “Optionee”), pursuant to which the Optionee had an option (the “Option”) to enter into an exclusive license to olinciguat for human therapeutics, subject to certain carveouts. Under the terms of the Option Agreement, the Optionee paid the Company an Option fee of \$150,000 in August 2024 and subsequent fees totaling \$80,000 to extend the term of the Option Agreement. The Optionee originally could exercise the Option on or before March 20, 2025, which option period was ultimately extended through August 22, 2025. Thereafter, the parties had an additional 60 days to negotiate the terms of a definitive license agreement. The parties were unable to agree upon the terms of a license agreement and the Company provided notice on October 23, 2025 that it was terminating the Option Agreement.

12. Subsequent Events

On January 6, 2026, the Company sold 405,000 shares of common stock under the Sales Agreement for net proceeds of approximately \$0.8 million. The Company exhausted all sales under the 2025 Shelf.

On January 3, 2026, the Company and the Medsteer, SAS (“Medsteer”) entered into a Collaboration and Option Agreement (the “Collaboration Agreement”) pursuant to which Medsteer granted to the Company (i) a non-exclusive, worldwide, royalty-free, sublicensable license of certain of Medsteer’s technology, software and intellectual property to develop an anesthetic delivery system with Medsteer and (ii) an exclusive option (the “Option”), exercisable at the Company’s sole discretion, to obtain an exclusive, worldwide, royalty-bearing, sublicensable license of certain of Medsteer’s technology, software and intellectual property to develop or commercialize licensed products in any field of use except for sedation regulation for patients undergoing major surgery, in multi-bed or intensive unit wards, or in the context of medical transport. The Company may exercise the Option at any time until the earlier of the second anniversary of the effective date of the Collaboration Agreement, which period may be extended for an addition two years at the Company’s option and upon payment of a nominal fee or by mutual agreement of the Company and Medsteer.

Under the terms of the Collaboration Agreement, the Company will pay to Medsteer a nominal upfront payment, a payment upon exercise of the Option, and Medsteer will be eligible to receive up to \$3.7 million upon the achievement of certain development, regulatory and sales milestone payments. Medsteer will also receive an annual royalty payment and royalties in a percentage in the low single digits based on future net sales of licensed products, subject to certain adjustments as set forth in the Collaboration Agreement.

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

General

The following description of our capital stock is intended as a summary only and is qualified in its entirety by reference to our articles of organization and bylaws, the Annual Report on Form 10-K to which this description is an exhibit, any and all of which may be amended from time to time, and to the applicable provisions of the Massachusetts Business Corporation Act ("MBCA").

Our authorized capital stock consists of 400,000,000 shares of our common stock and 100,000,000 shares of our preferred stock, all of which preferred stock is undesignated, except that 500,000 shares of our Preferred Stock are designated as Series A Convertible Preferred Stock. As of December 31, 2025 and March 27, 2026, there were 3,925,314 and 4,330,314 shares of common stock outstanding, respectively and 351,037 shares of Series A Convertible Preferred Stock outstanding.

Common Stock*Dividend Rights*

Subject to preferences that may apply to shares of preferred stock outstanding, holders of outstanding shares of common stock are entitled to receive dividends out of assets legally available at the times and in the amounts as our board of directors may from time to time determine.

Voting Rights

Each outstanding share of common stock is entitled to one vote on all matters submitted to a vote of shareholders. Holders of shares of our common stock have no cumulative voting rights.

Preemptive Rights.

Our common stock is not entitled to preemptive or other similar subscription rights to purchase any of our securities.

Conversion or Redemption Rights

Our common stock is neither convertible nor redeemable.

Liquidation Rights

Upon our liquidation, the holders of our common stock will be entitled to receive pro rata our assets which are legally available for distribution, after payment of all debts and other liabilities and subject to the prior rights of any holders of preferred stock then outstanding.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "CYCN."

Anti-takeover Effects of Our Articles of Organization and Our Bylaws

Our articles of organization and bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors. These provisions include:

Action by Written Consent and Special Meetings of Shareholders

Our articles of organization provide that shareholder action can be taken only at an annual or special meeting of shareholders or by the unanimous written consent of all shareholders in lieu of such a meeting. Our articles of organization and the bylaws also provide that, except as otherwise required by law, special meetings of the shareholders can only be called pursuant to a resolution adopted by a majority of our board of directors or holders of at least 40% of our then outstanding common stock. Except as described above, shareholders are not permitted to call a special meeting or to require our board of directors to call a special meeting.

Advance Notice Procedures

Our bylaws contain an advance notice procedure for shareholder proposals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to the board of directors. Shareholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a shareholder who was a shareholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the shareholder's intention to bring that business before the meeting. Although our bylaws do not give our board of directors the power to approve or disapprove shareholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Proxy Access

Our bylaws provide that a shareholder or a group of shareholders meeting certain conditions may nominate candidates for election as a director at an annual meeting of our shareholders using "proxy access" provisions. These provisions allow one or more shareholders (up to 20, collectively), owning at least 3% of our outstanding common stock continuously for at least three years, to nominate for election to our board of directors and to be included in our proxy materials up to the greater of two individuals or 20% of our board of directors, subject to the provisions included in our bylaws, including the provision of timely written notice to our Secretary.

Number of Directors and Filling Vacancies and Election of Directors

Our articles of organization provide that the number of directors is established by the board of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office. The ability of our board of directors to increase the number of directors and fill any vacancies may make it more difficult for our shareholders to change the composition of our board of directors. Our bylaws provide that a majority of the votes properly cast for the election of a director shall effect such election unless there are more nominees than directorships, in which case a plurality standard shall apply.

Authorized and Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without shareholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum.

Our articles of organization require, to the fullest extent permitted by law, that derivative actions brought in the name of Cycleron, actions against our directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the Commonwealth of Massachusetts. Although we believe this provision benefits us by providing increased consistency in the application of Massachusetts law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

Anti-Takeover Provisions under Massachusetts Law

Provisions Regarding Business Combinations

We are subject to the provisions of Chapter 110F of the MBCA. In general, Chapter 110F prohibits a publicly held Massachusetts corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, five percent or more of the corporation's voting stock.

Under Chapter 110F, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 90% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by our board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Massachusetts corporation may "opt out" of these provisions with an express provision in its original articles of organization or an express provision in its articles of organization or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Provisions Regarding a Classified Board of Directors

Section 8.06(b) of the MBCA provides that, unless a company opts out of such provision, the terms of directors of a public Massachusetts company shall be staggered by dividing the directors into three groups, as nearly equal in number as possible, with only one group of directors being elected each year. We plan to opt out of this default requirement for a classified board of directors, and expect that all of our directors serve for one-year terms and will be elected annually.

Pursuant to Section 8.06(c)(2) of the MBCA, however, our board of directors may unilaterally opt back into default requirements under Section 8.06(b) of the MBCA and become a classified board of directors without the approval of our stockholders. Sections 8.06(d) and (e) of the MBCA provide that when a board of directors is so classified, (i) stockholders may remove directors only for cause, (ii) the number of directors shall be fixed only by the vote of the board of directors, (iii) vacancies and newly created directorships shall be filled solely by the affirmative vote of a majority of the remaining directors and (iv) a decrease in the number of directors will not shorten the term of any incumbent director. If our board of directors opts into this classified structure in the future, these provisions are likely to increase the time required for stockholders to change the composition of our board of directors. For example, at least two annual meetings would generally be necessary for stockholders to effect a change in a majority of the members of our board of directors. As a result, the ability of our board of directors to adopt a classified structure in the future without the approval of our stockholders could have the effect of

discouraging a potential acquirer from making a tender offer for a majority of the outstanding voting interest of our capital stock or otherwise attempting to obtain control of Cycleron.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Indemnification of Directors and Officers

Our articles of organization provide that the liability of our directors for damages for any breach of fiduciary duty shall be limited to the fullest extent permitted by law. Our bylaws also provide that we will indemnify, and advance funds to and reimburse expenses of, our directors and officers that have been appointed by our board of directors to the fullest extent permitted by law, and that we may indemnify, and advance funds to and reimburse expenses of, such other officers and employees as determined by our board of directors. The right of indemnification provided under our bylaws is in addition to and not exclusive of any other rights to which any of our directors, officers or any other persons may otherwise be lawfully entitled. We have also entered, or expect to enter, into indemnification agreements with our directors and officers, and we carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacity as directors and officers.

Part 8 of the MBCA authorizes the provisions, described above, that are contained in our articles of organization and bylaws. In addition, Sections 8.30 and 8.42 of the MBCA provide that if an officer or director discharges his or her duties in good faith and with the care that a person in a like position would reasonably exercise under similar circumstances and in a manner the officer or director reasonably believes to be in the best interests of the corporation, he or she will not be liable for such action.

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.

COLLABORATION AND OPTION AGREEMENT

This COLLABORATION AND OPTION AGREEMENT (this “**Agreement**”) is entered into this 3rd day of January 2026 (the “**Effective Date**”), by and between Medsteer, SAS, having a business address at Hopital Foch, Service Anesthesie, 40 Rue Worth, 92151 Suresnes, France (“**Medsteer**”), and Cycleron Therapeutics, Inc., a Massachusetts corporation having offices at 245 First Street, Riverview II, 18th Floor, Cambridge, MA 02142, U.S.A. (“**Cycleron**”). Medsteer and Cycleron are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

WHEREAS, Medsteer is a technology provider in the field of closed loop systems for the delivery of anesthesia drugs;

WHEREAS, Cycleron is a biopharmaceutical company dedicated to advancing a personalized therapeutic approach for people living with neuropsychiatric diseases and disorders with an initial indication targeting treatment-resistant depression (TRD);

WHEREAS, the Parties previously entered into that certain Consulting Agreement, dated on October 7, 2025 (the “**Consulting Agreement**”) with respect to certain development activities relating to the Licensed Product, which Consulting Agreement the Parties agree to terminate and supersede with these Agreement;

WHEREAS, the Parties desire to conduct certain development activities, Cycleron desires to obtain an option to receive an exclusive license under certain Medsteer technology, and Medsteer desires to grant such option, in each case, on the terms set forth in this Agreement.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

The following terms, whether used in the singular or plural, will have the following meanings:

- 1.1. “**Accounting Standards**” means, with respect to a Party, as applicable, (a) United States Generally Accepted Accounting Principles or (b) International Financial Reporting Standards as issued by the International Accounting Standards Board, in each case, consistently applied.
- 1.2. “**Affiliate**” means, with respect to any Person, any Person controlling, controlled by or under common control with such Person. For purposes of this Section 1.2 (Affiliate), the term “control” (including, with correlative meaning, the terms “controlled by” and “under common control with”), means the possession, directly or indirectly, of more than 50% of the voting stock or other ownership interest of such Person, or the possession, directly or indirectly, of the power to direct or cause the direction of the affairs or management and policies of such Person or the power to elect or appoint more than 50% of the members of the governing body of such Person. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside the United States, the maximum percentage ownership permitted by Applicable Law for a foreign investor may be less than 50%, and that in such case such lower percentage will be substituted in the preceding sentence; *provided* that such foreign investor has the power to direct the management

and policies of such entity.

- 1.3. “**Agreement**” has the meaning set forth in the Preamble.
- 1.4. “**Alleged Breaching Party**” has the meaning set forth in Section 10.2.2 (Termination for Material Breach).
- 1.5. “**Annual Minimum Royalty Payment**” has the meaning set forth in Section 5.3.1 (Minimum Royalty Payment).
- 1.6. “**Applicable Law**” means any applicable federal, state, local, municipal, foreign, or other law, statute, legislation, principle of common law, ordinance, code, rule, regulation, or other pronouncement issued, enacted, adopted, passed, approved, promulgated, made, implemented, or otherwise put into effect by or under the authority of any Governmental Authority, including the applicable regulations and guidance of the FDA and European Union (and national implementations thereof) that constitute cGLP practices.
- 1.7. “**Audited Party**” has the meaning set forth in Section 5.4.1 (Books and Records).
- 1.8. “**Auditing Party**” has the meaning set forth in Section 5.4.1 (Books and Records).
- 1.9. “**Auditor**” has the meaning set forth in Section 5.4.1 (Books and Records).
- 1.10. “**Background Know-How**” has the meaning set forth in Section 6.1 (Background Technology).
- 1.11. “**Background Patent Right**” has the meaning set forth in Section 6.1 (Background Technology).
- 1.12. “**Background Technology**” has the meaning set forth in Section 6.1 (Background Technology).
- 1.13. “**Blocking Third Party Intellectual Property**” means, with respect to a Licensed Product in a country, Patent Rights or Know-How owned or controlled by a Third Party (but not then included in the Medsteer Background Technology) that Cover (with respect to Patent Rights) or are otherwise necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale, import, or Commercialize (with respect to Know-How) such Licensed Product in such country.
- 1.14. “**Blocking Third Party Intellectual Property Costs**” means, royalty payments paid by Cycleron or its Affiliates or Sublicensees to a Third Party that owns or controls Blocking Third Party Intellectual Property (or that, prior to the applicable transaction with Cycleron or its Affiliates or Sublicensees, owned or controlled Blocking Third Party Intellectual Property) to license or acquire such Blocking Third Party Intellectual Property.
- 1.15. “**Business Day**” means a day that is not a Saturday, Sunday, or a day on which banking institutions in New York City, New York, U.S.A. or Paris, France are authorized or required by Applicable Law to remain closed.
- 1.16. “**C.F.R.**” means the U.S. Code of Federal Regulations.
- 1.17. “**Calendar Quarter**” means each period of three consecutive calendar months ending on March 31, June 30, September 30, or December 31, except that the first Calendar Quarter of the Term will commence on the Effective Date, and the last Calendar Quarter of the Term will end on the effective date of the termination or expiration of this Agreement.

- 1.18.** “**Calendar Year**” means each period of 12 consecutive calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term will commence on the Effective Date, and the last Calendar Year of the Term will end on the effective date of the termination or expiration of this Agreement.
- 1.19.** “**cGLP**” means the then-current good laboratory practice as required by the FDA under 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to current good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the International Conference on Harmonization (ICH) Guidelines, or as otherwise required by Applicable Law.
- 1.20.** “**Change of Control**” means, with respect to a Party, (a) a merger, reorganization, combination, or consolidation of such Party with a Third Party that results in the holders of beneficial ownership of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, combination, or consolidation ceasing to hold beneficial ownership of more than 50% of the combined voting power of the surviving entity or the ultimate parent of the surviving entity immediately after such merger, reorganization, combination or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of 50% or more of the combined voting power of the outstanding securities or other voting interest of such Party, (c) the sale, lease, exchange, contribution, or other transfer (in one transaction or a series of related transactions) to a Third Party of all or substantially all of such Party’s assets, or (d) a liquidation or dissolution of such Party or any direct or indirect parent of such Party.
- 1.21.** “**Clinical Trial**” means any clinical investigation conducted on human subjects, as that term is defined in FDA regulations at 21 C.F.R. § 312.3, or a similar clinical investigation conducted on human subjects, as defined under Applicable Law outside the United States
- 1.22.** “**Collaboration Activities**” has the meaning set forth in Section 2.1.1 (Collaboration Plan).
- 1.23.** “**Collaboration Plan**” has the meaning set forth in Section 2.1.1 (Collaboration Plan).
- 1.24.** “**Collaboration Term**” means the period beginning on the Effective Date and ending on the earlier of (a) the License Effective Date or (b) the expiration of the Cycleron Option Exercise Period.
- 1.25.** “**Commercialization**” or “**Commercialize**” means with respect to any product, any and all activities directed to the marketing, promotion, patient services, distribution, pricing, reimbursement, pharmacovigilance, import, export, offering for sale, and sale of such product, and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such product regarding the foregoing, but excluding any activities directed to Development. “**Commercialize**,” “**Commercializing**,” and “**Commercialized**” will be construed accordingly.
- 1.26.** “**Competing Product**” [***].
- 1.27.** “**Competitive Infringement**” on a Licensed Product-by-Licensed Product and country-by-country basis, the infringement, unauthorized use, misappropriation or threatened infringement by a Third Party with respect to any Medsteer Background Technology by reason of the making, using, offering to sell, selling, importing or other exploitation of a technology or product that would be competitive with a Licensed Product in the Cycleron Field in the Territory.

- 1.28. “**Confidential Information**” means (a) the existence and terms of this Agreement, and (b) with respect to each Party, Know-How, materials, and other proprietary information, including data and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial, and commercial information or data that is disclosed, made available to, or provided by or on behalf of such Party to the other Party or to any of the Receiving Party’s employees, consultants, Affiliates, or Sublicensees, whether or not specifically marked or designated by the Disclosing Party as confidential.
- 1.29. “**Confidentiality Agreement**” has the meaning set forth in Section 7.1.2 (Confidential Information of Each Party).
- 1.30. “**Consulting Agreement**” has the meaning set forth in the Preamble.
- 1.31. “**Control**” or “**Controlled**” means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any materials or other tangible Know-How, the legal authority or right to physical possession of such materials or tangible Know-How, with the right to provide such materials or tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a 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 or incurring any additional payment obligations to a Third Party as a result of such access, right to use, license, or sublicense, and (c) with respect to any product, the legal authority or right to grant an exclusive license or sublicense under Patent Rights that Cover such product or Know-How that relates to such product. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to “**Control**” any of the foregoing (a) – (c) that prior to the consummation of a Change of Control of such Party, 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 Change of Control.
- 1.32. “**Cover**,” “**Covers**,” or “**Covered**” means, as to a product or other technology and Patent Right, that, in the absence of a license granted under, or ownership of, such Patent Right, the making, using, keeping, selling, offering for sale or importation of such compound, product or other technology would infringe such Patent Right or, as to a pending claim included in such Patent Right, the making, using, keeping, selling, offering for sale or importation of such product or other technology would infringe such Patent Right if such pending claim were to issue in an issued patent without modification.
- 1.33. “**Cyclerion**” has the meaning set forth in the Preamble.
- 1.34. “**Cyclerion Background Know-How**” means any Background Know-How that is Controlled by Cyclerion or any of its Affiliates as of the Effective Date or thereafter during the Term.
- 1.35. “**Cyclerion Background Patent Right**” means any Background Patent Right that is Controlled by Cyclerion or any of its Affiliates as of the Effective Date or thereafter during the Term.
- 1.36. “**Cyclerion Background Technology**” means the Materials, Cyclerion Background Know-How,

and Cyclерion Background Patent Rights.

- 1.37. “**Cyclерion Extended Option Exercise Period**” has the meaning set forth in Section 3.1.2 (Cyclерion Option Exercise)
- 1.38. “**Cyclерion Field**” means any and all uses, excluding the Medsteer Field.
- 1.39. “**Cyclерion Improvements**” has the meaning set forth in Section 6.2.5(b) (Cyclерion Disclosure of Improvements to Medsteer Background Technology).
- 1.40. “**Cyclерion Indemnitees**” has the meaning set forth in Section 9.2 (Indemnification by Medsteer).
- 1.41. “**Cyclерion Initial Option Exercise Period**” has the meaning set forth in Section 3.1.2 (Cyclерion Option Exercise)
- 1.42. “**Cyclерion Option**” has the meaning set forth in Section 3.1.1 (Option Grant to Cyclерion).
- 1.43. “**Cyclерion Option Exercise Notice**” has the meaning set forth in Section 3.1.2 (Cyclерion Option Exercise).
- 1.44. “**Cyclерion Option Exercise Payment**” has the meaning set forth in Section 5.1.2 (Cyclерion Option Exercise Payment).
- 1.45. “**Cyclерion Option Exercise Period**” has the meaning set forth in Section 3.1.2 (Cyclерion Option Exercise)
- 1.46. “**Cyclерion Product**” means any device that (a) is developed by or on behalf of Cyclерion and (b) is an open- or closed-loop system that processes EEG data, computes an infusion rate, and either outputs that rate or delivers anesthesia drugs.
- 1.47. “**Deposit Materials**” has the meaning set forth in Section 4.3.1 (Software Escrow).
- 1.48. “**Development**” or “**Develop**” means, with respect to any product, any and all internal and external research, development, pharmacovigilance activities, and regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, IND-enabling studies, and Clinical Trials, 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, support, or maintain Regulatory Approval of such product, but excluding any activities directed to Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such country). “**Develop**,” “**Developing**,” and “**Developed**” will be construed accordingly.
- 1.49. “**Disclosing Party**” has the meaning set forth in Section 7.1.1 (General).
- 1.50. “**Dollar**” means the U.S. dollar, and “**\$**” will be interpreted accordingly.

- 1.51. “**Effective Date**” has the meaning set forth in the Preamble.
- 1.52. “**EMA**” means the European Medicines Agency or any successor agency or authority thereto.
- 1.53. “**Escrow Agent**” has the meaning set forth in Section 4.3.1 (Software Escrow).
- 1.54. “**European Union**” or “**EU**” means (a) all countries or territories that are officially part of the European Union, as constituted from time to time, and (b) the United Kingdom.
- 1.55. “**Extended Option Exercise Period**” has the meaning set forth in Section 3.1.2 (Cyclerion Option Exercise).
- 1.56. “**FD&C Act**” means the United States Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder, as may be in effect from time to time.
- 1.57. “**FDA**” means the United States Food and Drug Administration and any successor agency or authority thereto.
- 1.58. “**FDA Clearance**” means receipt of any approval from the FDA that is required to conduct a Phase 3 Clinical Trial of a Licensed Product in the United States.
- 1.59. “**First Commercial Sale**” means, on a Licensed Product-by-Licensed Product and country-by-country basis, the date of the first sale of a Licensed Product in such country by Cyclerion or its Affiliate or Sublicensee to a Third Party for end use or consumption following receipt of any required Regulatory Approval for such Licensed Product in such country, excluding any named patient sales or any sale or other distribution at cost or less than cost for use in any Clinical Trial, for *bona fide* charitable purposes, test marketing program, or for compassionate use.
- 1.60. “**Governmental Authority**” means any arbitrator, court, judicial, legislative, administrative or regulatory authority, commission, department, board, bureau, or body, or other government authority or instrumentality or any Person exercising executive, legislative, judicial, regulatory, or administrative functions of or pertaining to government, whether foreign or domestic, whether federal, state, provincial, municipal, or other.
- 1.61. “**Indemnitee**” has the meaning set forth in Section 9.3 (Indemnification Procedure).
- 1.62. “**Infringement**” has the meaning set forth in Section 6.3.1 (Notification).
- 1.63. “**Infringement Action**” has the meaning set forth in Section 6.3.2(a) (Competitive Infringements).
- 1.64. “**Initial Option Exercise Period**” has the meaning set forth in Section 3.1.2 (Cyclerion Option Exercise).
- 1.65. “**Insolvency Event**” has the meaning set forth in Section 10.2.3 (Termination for Insolvency).
- 1.66. “**Insolvent Party**” has the meaning set forth in Section 10.2.3 (Termination for Insolvency).
- 1.67. “**Intellectual Property Rights**” means any Know-How, Patent Rights, Trademarks, copyrights, trade secrets, and any other intellectual property rights however denominated throughout the world.
- 1.68. “**Joint Committee**” or “**JC**” has the meaning set forth in Section 2.2.1 (Formation and Purpose).

- 1.69. “**Know-How**” means any information and materials, including records, discoveries, improvements, modifications, processes, techniques, methods, assays, chemical or biological materials, 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, inventions, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how and trade secrets (in each case, patentable, copyrightable or otherwise).
- 1.70. “**License Effective Date**” has the meaning set forth in Section 3.1.3 (Effects of Option Exercise).
- 1.71. “**Licensed Product**” means any Cycleron Product that (a) is Covered by an issued claim of a Medsteer Background Patent Right or (b) incorporates the Medsteer Background Software.
- 1.72. “**Losses**” has the meaning set forth in Section 9.1 (Indemnification by Cycleron).
- 1.73. “**Materials**” has the meaning set forth in Section 2.1.4 (Cycleron Materials).
- 1.74. “**Medsteer**” has the meaning set forth in the Preamble.
- 1.75. “**Medsteer Background Know-How**” means any Background Know-How that (a) is Controlled by Medsteer or any of its Affiliates as of the Effective Date or thereafter during the Term and (b) is generally described in **Schedule 1.75** (Medsteer Background Know-How). For clarity, Know-How Controlled by Medsteer and solely relating to the dual and simultaneous closed loop regulation of Propofol-Remifentanyl is not part of the Medsteer Background Know-How.
- 1.76. “**Medsteer Background Patent Right**” means any Background Patent Right that (a) is Controlled by Medsteer or any of its Affiliates as of the Effective Date or thereafter during the Term and (b) either (i) claims any Medsteer Background Know-How or the Medsteer Background Software or (ii) is otherwise identified in **Schedule 1.76** (Medsteer Background Patent Rights).
- 1.77. “**Medsteer Background Software**” means Medsteer’s proprietary [***], in each case ((a) – (c)), which were in existence prior to the effective date of the Consulting Agreement or thereafter during the Term and that are necessary or reasonably useful to (i) conduct activities under the Collaboration Plan or (ii) exploit the product that is the subject of the Collaboration Plan, including any of the foregoing within the Part A and Part B source code described in the Collaboration Plan. [***].
- 1.78. “**Medsteer Background Technology**” means the (a) Medsteer Background Know-How, (b) Medsteer Background Patent Rights, and (c) Medsteer Background Software (including all Intellectual Property Rights therein).
- 1.79. “**Medsteer Field**” means the field of sedation regulation for patients undergoing major surgery, sedation regulation for patients hospitalized in multi-bed intensive care unit or general intensive care unit wards, and sedation regulation for patients in the context of medical transport (e.g., medevacs).
- 1.80. “**Medsteer Indemnitees**” has the meaning set forth in Section 9.1 (Indemnification by Cycleron).
- 1.81. “**Medsteer In-License Agreements**” has the meaning set forth in Section 3.8 (Medsteer In-License Agreements).

- 1.82. “**Medsteer Option**” has the meaning set forth in Section 6.2.3 [***].
- 1.83. “**Medsteer Option Exercise Notice**” has the meaning set forth in Section 6.2.3 [***].
- 1.84. “**Medsteer Option Exercise Period**” has the meaning set forth in Section 6.2.3 [***].
- 1.85. “**Milestone Event**” has the meaning set forth in Section 5.2.1 (Milestone Payments).
- 1.86. “**Milestone Payment**” has the meaning set forth in Section 5.2.1 (Milestone Payments).
- 1.87. “**Net Sales**” means the gross invoiced amount on sales of the Licensed Products by Cyclerion and its Affiliates and Sublicensees to Third Parties (including distributors), less the following deductions in accordance with Accounting Standards and the accrual method of accounting, consistently applied with respect to such sales:
- (a) [***];
 - (b) [***];
 - (c) [***];
 - (d) [***];
 - (e) [***].
- [***].
- 1.88. “**Non-Breaching Party**” has the meaning set forth in Section 10.2.2 (Termination for Material Breach).
- 1.89. “**Non-Withholding Party**” has the meaning set forth in Section 5.6 (Withholding Taxes).
- 1.90. “**Party**” has the meaning set forth in the Preamble.
- 1.91. “**Patent Rights**” means all rights, title, and interests in and to (a) all national, regional, and international patents and patent applications filed in any country of the world, including provisional patent applications and all supplementary protection certificates, (b) all patent applications filed either from such patents, patent applications, or provisional applications or from an application claiming priority to any of the foregoing, including any continuation, continuation-in part, divisional, provisional, converted provisionals and continued prosecution applications, or any substitute applications, (c) any patent issued with respect to or in the future issued from any such patent applications, including utility models, petty patents, design patents and certificates of invention, and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, reexaminations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.
- 1.92. “**Payments**” has the meaning set forth in Section 5.6 (Withholding Taxes).
- 1.93. “**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited

liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including any Governmental Authority (or any department, agency, or political subdivision thereof).

- 1.94.** “**Phase 3 Clinical Trial**” means any Clinical Trial as described in 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent Clinical Trial.
- 1.95.** “**Program Know-How**” has the meaning set forth in Section 6.2.1 (Ownership of Program Know-How).
- 1.96.** “**Program Patent Rights**” has the meaning set forth in Section 6.2.2 (Ownership of Program Patent Rights).
- 1.97.** “**Proposed Transaction**” has the meaning set forth in Section 3.12 (Right of First Negotiation).
- 1.98.** “**Receiving Party**” has the meaning set forth in Section 7.1.1 (General).
- 1.99.** “**Regulatory Approval**” means, with respect to a Licensed Product in any country or jurisdiction, any approval, registration, license, or authorization from a Regulatory Authority in a country or other jurisdiction that is necessary to market and sell such Licensed Product in such country or jurisdiction.
- 1.100.** “**Regulatory Authority**” means any Governmental Authority or authority responsible for granting Regulatory Approvals, including the FDA, EMA, and any corresponding national or regional regulatory authorities.
- 1.101.** “**Regulatory Submissions**” means any regulatory application, submission, notification, communication, correspondence, registration, Regulatory Approval, and other filing, made to, received from or otherwise conducted with a Regulatory Authority related to Developing, manufacturing, obtaining marketing authorization, or otherwise Commercializing a product in a particular country or jurisdiction, including all applications for Regulatory Approval, together with all supplements or amendments to any of the foregoing.
- 1.102.** [***].
- 1.103.** “**Royalty Rates**” has the meaning set forth in Section 5.3.1 (Royalties).
- 1.104.** “**Royalty Report**” has the meaning set forth in Section 5.3.4 (Royalty Reports; Payments).
- 1.105.** “**Royalty Term**” means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period commencing on the first sale of such Licensed Product giving rise to Net Sales in such country and ending upon the latest of: (a) the expiration of the last issued claim of a Medsteer Background Patent Right that Covers such Licensed Product in such country; and (b) the last date on which any Medsteer Background Software is incorporated in such Licensed Product in such country.
- 1.106.** [***].
- 1.107.** “**Sublicensee**” has the meaning set forth in Section 3.6 (Sublicenses).
- 1.108.** “**Tax**” or “**Taxation**” means any form of tax or taxation, levy, duty, charge, social security charge,

contribution or withholding of whatever nature (including any related fine, penalty, surcharge, or interest) imposed by, or payable to, a tax authority.

- 1.109.** “**Technology Transfer Plan**” has the meaning set forth in Section 4.1 (Technology Transfer).
- 1.110.** “**Term**” has the meaning set forth in Section 10.1 (Term).
- 1.111.** “**Territory**” means worldwide.
- 1.112.** “**Third Party**” means any Person other than a Party or an Affiliate of a Party.
- 1.113.** “**Third Party License**” means a written agreement between a Party or its Affiliates and a Third Party to license or acquire Third Party Intellectual Property Rights for use in connection with the Development or Commercialization of a Licensed Product.
- 1.114.** “**Trademarks**” means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, symbols, designs, and all other indicia of ownership, and combinations thereof.
- 1.115.** “**United States**” or “**U.S.**” means the United States of America and all of its districts, territories and possessions.
- 1.116.** “**Upfront Payment**” has the meaning set forth in Section 5.1.1 (Upfront Payment).
- 1.117.** “**Withholding Party**” has the meaning set forth in Section 5.6 (Withholding Taxes).

ARTICLE 2 COLLABORATION ACTIVITIES

2.1. Collaboration Activities.

- 2.1.1. Collaboration Plan.** The Development activities planned to be conducted during the Cycleron Option Exercise Period are set forth on Schedule 2.1.1 (Collaboration Plan), which plan includes: (a) the specific Development activities to be conducted by or on behalf of Medsteer in furtherance of the Development of the Licensed Product, (b) the estimated timelines for performance of such activities and (c) the fees payable by Cycleron to Medsteer in connection with the conduct of such activities (as such plan may be amended from time to time in accordance with this Agreement, the “**Collaboration Plan**,” the activities to be performed under the Collaboration Plan, the “**Collaboration Activities**”). The Parties may amend the Collaboration Plan solely upon mutual written agreement.
- 2.1.2. Fees.** Cycleron agrees to pay Medsteer the fees and reasonable expenses set forth in the Collaboration Plan. Unless otherwise specified in the Collaboration Plan, Medsteer will invoice Cycleron on a monthly basis and will submit the invoice for each calendar month no later than [***] following the end of such calendar month. Cycleron will pay Medsteer all undisputed payments that have been properly invoiced within [***] from Cycleron’s receipt of Medsteer’s applicable invoice. Each invoice will contain such detail as Cycleron may reasonably require, and will be quoted in and payable in U.S. Dollars. Medsteer consents to Cycleron’s disclosure of such fees and expenses from time to time, if and when required by Applicable Law.
- 2.1.3. Performance.** Medsteer agrees to perform the Collaboration Activities (a) at such reasonably

convenient times and places as Cyclerion may direct and (b) in a professional, diligent, timely and workmanlike manner consistent with the highest industry standards prevailing for comparable services and in accordance with the Collaboration Plan and this Agreement. Medsteer will comply with all rules, procedures and standards promulgated from time to time by Cyclerion with regard to Medsteer's access to and use of Cyclerion's property, information, equipment and facilities, as well as those related to standards of conduct while performing the Collaboration Activities on behalf of Cyclerion. Medsteer agrees to furnish Cyclerion with written reports with respect to the Collaboration Activities if and when requested by Cyclerion. Cyclerion will have the right to reject, and shall have no obligation to pay for, the performance of any Collaboration Activities that do not meet the requirements or quality criteria set forth in the Collaboration Plan and this Agreement.

- 2.1.4. Cyclerion Materials.** All documentation, information, and biological, chemical and other materials controlled by Cyclerion and furnished to Medsteer by or on behalf of Cyclerion ("**Materials**") and all associated Intellectual Property Rights will remain the exclusive property of Cyclerion. Medsteer will use Materials provided by Cyclerion only as necessary to perform the Collaboration Activities, and will treat such Materials in accordance with the requirements of the Collaboration Plan and this Agreement. Medsteer agrees that it will not use or evaluate the Materials or any portions thereof for any other purpose except as directed or permitted in writing by Cyclerion. Without Cyclerion's prior express written consent, Medsteer agrees that it will not analyze the Materials, or transfer or make the Materials available to Third Parties.
- 2.1.5. Work at Third Party Facilities.** Medsteer will not use any Third Party facilities or Third Party Intellectual Property Rights in performing the Collaboration Activities without Cyclerion's prior written consent.
- 2.2. Joint Committee.**
- 2.2.1. Formation and Purpose.** Promptly, but no later than 30 days after the Effective Date, the Parties will establish a Joint Committee ("**JC**"), which JC will coordinate and oversee or monitor the Parties' activities hereunder in accordance with this Section 2.2.1 (Formation and Purpose).
- 2.2.2. Membership.** Each Party will designate at least one representative (with an equal number of representatives from each Party at all times) with appropriate expertise and seniority to serve as members of the JC. Each Party may replace its JC representatives at any time upon written notice to the other Party.
- 2.2.3. Meetings.** The JC will hold meetings no less frequently than bi-weekly unless otherwise agreed by the Parties. The JC may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (b) by audio or video teleconference. Each Party will be responsible for all of its own costs and expenses of participating in any JC meeting, unless otherwise agreed upon by the Parties in writing.
- 2.2.4. Specific Responsibilities of the JC.** The responsibilities of the JC will be to:
- (a) oversee the overall strategic relationship between the Parties;
 - (b) review and discuss the Collaboration Activities; and
 - (c) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

- 2.2.5. Limitation of Authority.** The JC will have only such powers as are specifically delegated to it hereunder and will not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, the JC will not have any power to amend this Agreement, waive compliance with any obligation or term hereunder or determine whether any breach hereunder has occurred.
- 2.2.6. Discontinuation of the JC.** The JC will automatically disband at the end of the Collaboration Term.

ARTICLE 3
CYCLERION OPTION, LICENSE AND NON-COMPETE

3.1. Cyclерion Exclusive Option.

- 3.1.1. Option Grant to Cyclерion.** Medsteer hereby grants to Cyclерion an exclusive option, exercisable at Cyclерion's sole discretion as set forth in Section 3.1.2 (Cyclерion Option Exercise), to obtain the licenses set forth in Section 3.3 (Commercial License Grant to Cyclерion) (the "**Cyclерion Option**").
- 3.1.2. Cyclерion Option Exercise.** Cyclерion may exercise the Cyclерion Option by delivering written notice of such exercise (such notice, the "**Cyclерion Option Exercise Notice**") to Medsteer at any time during the period commencing on the Effective Date and ending on the latest of (a) the second anniversary of the Effective Date (the "**Cyclерion Initial Option Exercise Period**"), (b) if, at any time during the Cyclерion Initial Option Exercise Period, Cyclерion notifies Medsteer in writing that it desires to extend the Cyclерion Initial Option Exercise Period and submits to Medsteer a one-time payment of [***], then the fourth anniversary of the Effective Date ("**Cyclерion Extended Option Exercise Period**"), and (c) if, at any time during the Cyclерion Initial Option Exercise Period or the Cyclерion Extended Option Exercise Period, the Parties mutually agree in writing to extend the Cyclерion Extended Option Exercise Period and Cyclерion submits to Medsteer a one-time payment of [***], then [***] of the Effective Date (such period described in this Section 3.1.2 (Cyclерion Option Exercise) during which Cyclерion may exercise the Cyclерion Option, the "**Cyclерion Option Exercise Period**").
- 3.1.3. Effects of Cyclерion Option Exercise.** Upon (a) Cyclерion's delivery to Medsteer within the Cyclерion Option Exercise Period of the Cyclерion Option Exercise Notice and (b) payment of the Cyclерion Option Exercise Payment in accordance with Section 5.1.2 (Cyclерion Option Exercise Payment) (the first date on which both (a) and (b) have occurred, the "**License Effective Date**") Medsteer will grant Cyclерion the licenses set forth in Section 3.2 (Development License Grant to Cyclерion).
- 3.2. Development License Grant to Cyclерion.** Subject to the terms of this Agreement, Medsteer will grant and hereby grants to Cyclерion a non-exclusive, worldwide, royalty-free, sublicensable (solely in accordance with Section 3.5 (Sublicenses)) license under the Medsteer Background Technology solely to perform the Collaboration Activities during the Term.
- 3.3. Commercial License Grant to Cyclерion.** Subject to the terms of this Agreement, effective on the License Effective Date, Medsteer will grant and hereby grants to Cyclерion an exclusive (even as to Medsteer), worldwide, royalty-bearing, sublicensable (solely in accordance with Section 3.5 (Sublicenses)) license under the Medsteer Background Technology to make, have made, use, sell, offer for sale, import, or otherwise Develop or Commercialize Licensed Products in the Cyclерion Field in the Territory.

3.4. License Grants to Medsteer.

- 3.4.1. Program Patent Rights.** Subject to the terms of this Agreement, Cycleron hereby grants to Medsteer an exclusive, worldwide, perpetual, royalty-free, sublicensable license to use the Program Patent Rights to Develop (but not Commercialize) products in the Medsteer Field. [***].
- 3.4.2.** [***].
- 3.5. Cross-License to Joint Program Know-How.** Subject to the terms of this Agreement, (a) Cycleron hereby grants to Medsteer a worldwide, perpetual, royalty-free, sublicensable license under Cycleron's interest in the Program Know-How to Develop and Commercialize products in the Medsteer Field, and (b) Medsteer hereby grants to Cycleron a worldwide, perpetual, royalty-free, sublicensable license under Medsteer's interest in the Program Know-How to Develop and Commercialize products in the Cycleron Field.
- 3.6. Sublicenses.** Subject to the terms of this Agreement, including this Section 3.6 (Sublicenses) Cycleron may grant sublicenses under any rights granted by Medsteer under Section 3.2 (Development License Grant to Cycleron), Section 3.5 (Cross-License to Joint Program Know-How) or, from and after the License Effective Date, under Section 3.3 (Commercial License Grant to Cycleron) through multiple tiers to one or more Affiliates or Third Parties (each, a "**Sublicensee**"); *provided* that, to the extent Cycleron engages a Sublicensee to manufacture Licensed Product using Medsteer's Background Technology, that such Sublicensee is recognized as a reputable manufacturer in the industry.
- 3.7. Subcontractors.** Each Party may perform any of its obligations under this Agreement through one or more subcontractors; *provided* that (a) if such subcontractor is to be granted a sublicense under of any rights granted by Medsteer under Section 3.2 (Development License Grant to Cycleron), Section 3.3 (Commercial License Grant to Cycleron), or Section 3.5 (Cross-License to Joint Program Know-How), then the applicable terms of Section 3.6 (Sublicenses) will also apply, (b) the subcontracting Party will not engage any subcontractor that has been debarred by any Regulatory Authority; and (c) the subcontracting Party will be liable for any act or omission of any subcontractor that is a breach of any of the subcontracting Party's obligations under this Agreement as though the same were a breach by the subcontracting Party.
- 3.8. Medsteer In-License Agreements.** Certain of the MedSteer Background Technology Controlled by Medsteer as of the Effective Date was in-licensed or acquired by Medsteer under the agreements with Third Party licensors or sellers listed on Schedule 3.8 (such agreements, the "**Medsteer In-License Agreements**"). Any payment obligations arising under the Medsteer In-License Agreements as a result of the Development, manufacture, and Commercialization of a Licensed Product by or on behalf of Cycleron under this Agreement will be paid solely by Medsteer.
- 3.9. No Implied Licenses; Retained Rights.** Each Party acknowledges that the rights and licenses granted under this Agreement are limited to the scope expressly granted herein. Except for the rights expressly granted under this Agreement, no rights, title, licenses, or other interests of any nature whatsoever are granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. Medsteer reserves all rights to Medsteer Background Technology that are not specifically granted to Cycleron, and Cycleron reserves all rights to Cycleron Background Technology that are not specifically granted to Medsteer, in each case, under this Agreement.
- 3.10. Non-Compete.**

- 3.10.1. Medsteer Non-Compete.** During the Collaboration Term, neither Medsteer nor its Affiliates shall, [***], (a) [***], or (b) [***].
- 3.10.2. Cyclerion Non-Compete.** During the Collaboration Term, neither Cyclerion nor its Affiliates shall, [***], (a) [***], or (b) [***].
- 3.11. Non-Solicitation.** Prior to the one-year anniversary of the Effective Date, Medsteer shall not (a) solicit any person who is employed by or a consultant to Cyclerion or any Affiliate of Cyclerion, to terminate such person's employment by or consultancy to Cyclerion or such Affiliate, or (b) hire such employee or consultant. As used herein, the term "solicit" shall include, without limitation, requesting, encouraging, assisting or causing, directly or indirectly, any such employee or consultant to terminate such person's employment by or consultancy to Cyclerion or its Affiliate. Medsteer is under no obligation to solicit, refer, or solicit the referral of patients for any Cyclerion business. Medsteer will receive no benefit of any kind from Cyclerion for such referrals, nor suffer any detriment for not making such referrals.
- 3.12. Right of First Negotiation.**
- 3.12.1. Right of First Negotiation.** In the event Medsteer (a) initiates discussions, or makes a board-level decision to initiate discussions, with any Third Party or solicits any indications of interest, or makes a board-level decision to solicit any indications of interest, from any Third Party regarding any sale, assignment, license, sublicense, or other transfer of any right, title, or interest in or to the Program Know-How, or (b) receives any written communication, including any unsolicited written offer from any Third Party, regarding any sale, assignment, license, sublicense, or other transfer of any right, title, or interest in or to the Program Know-How (each ((a) and (b)), a "**Proposed Transaction**"), Medsteer shall first provide written notice to Cyclerion describing in reasonable detail the material terms of the Proposed Transaction. [***].
- 3.12.2.** [***].
- 3.12.3.** [***].

ARTICLE 4 TECHNOLOGY TRANSFER; SOFTWARE ESCROW

- 4.1. Technology Transfer.** No later than [***] following the License Effective Date, the Parties will negotiate in good faith a technology transfer plan with respect to the transfer to Cyclerion or a Third Party designated by Cyclerion and reasonably acceptable to Medsteer of [***] (the "**Technology Transfer Plan**"). Promptly after such technology transfer plan is agreed to by the Parties pursuant to this Section 4.1 (Technology Transfer) and in no event later than [***] after the date of the Parties' agreement on such Technology Transfer Plan, Medsteer will work with Cyclerion to transfer, or have transferred, if applicable, to Cyclerion (or its designee, pursuant to an appropriate confidentiality agreement with Medsteer) [***] set forth in the Technology Transfer Plan, to the extent not previously transferred to Cyclerion under this Agreement, [***].
- 4.2. Medsteer Technology Transfer Support.** If Cyclerion requests support from Medsteer or its representatives in connection with performance of activities under the Technology Transfer Plan, then to the extent that Medsteer is able to provide such support, Medsteer may invoice Cyclerion for the costs and expenses incurred in connection with providing such assistance and cooperation, and Cyclerion will pay all such invoiced amounts no later than [***] after the date of such invoice.

4.3. **Medsteer Background Software Escrow.**

- 4.3.1. Software Escrow.** Within [***] following the Effective Date, Medsteer shall, at Cyclерion’s sole cost, deposit with an independent, reputable third-party escrow agent reasonably acceptable to Cyclерion ([***]) (the “**Escrow Agent**”) [***] (collectively, the “**Deposit Materials**”). Medsteer shall update the Deposit Materials [***].
- 4.3.2. Release Conditions.** The Escrow Agent shall release the Deposit Materials to Cyclерion upon [***]. The Escrow Agent shall release the Deposit Materials within [***].
- 4.3.3. Confidentiality; Security.** The Deposit Materials constitute Medsteer’s Confidential Information. The Escrow Agent shall protect the Deposit Materials using industry-standard administrative, technical, and physical safeguards, including encryption at rest and in transit and multi-factor access controls. Cyclерion’s use of the Deposit Materials following release shall remain subject to the confidentiality obligations in this Agreement.
- 4.3.4. Coordination with Escrow Agreement.** Medsteer shall execute an escrow agreement with the Escrow Agent naming Cyclерion as a third-party beneficiary with direct enforcement rights consistent with this Section. In the event of any conflict between the escrow agreement and this Section, this Section shall control as between Medsteer and Cyclерion.
- 4.3.5. Clinical Datasets.** [***].

ARTICLE 5 FINANCIAL TERMS

5.1. **Upfront Payment; Cyclерion Option Exercise Payment.**

- 5.1.1. Upfront Payment.** Within [***] following the Effective Date, in consideration of the Cyclерion Option granted hereunder, Cyclерion will pay to Medsteer a one-time, non-refundable, non-creditable upfront payment of [***] (the “**Upfront Payment**”).
- 5.1.2. Cyclерion Option Exercise Payment.** Within [***] following Cyclерion’s delivery of the Cyclерion Option Exercise Notice pursuant to Section 3.1.2 (Cyclерion Option Exercise), Cyclерion will pay to Medsteer a one-time, non-refundable, and non-creditable payment of [***] (the “**Cyclерion Option Exercise Payment**”).

5.2. **Milestone Payments.**

- 5.2.1. Milestone Payments.** Cyclерion will pay Medsteer the amounts set forth in Table 5.2.1 below (each, a “**Milestone Payment**”) no later than [***] after the first occurrence of the corresponding event described below (each, a “**Milestone Event**”) for the first Licensed Product to achieve such Milestone Event. Each Milestone Payment is payable only once during the Term upon the first achievement of such Milestone Event with respect to a Licensed Product by Cyclерion or its Affiliates or Sublicensees, regardless of the number of times such milestone is achieved with respect to one or more Licensed Products.

Table 5.2.1 –Milestones	
Milestone Event	Milestone Payment
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
4. [***]	[***]
5. [***]	[***]
6. [***]	[***]

5.3. Royalty Payments.

5.3.1. Minimum Royalty Payment. For the period beginning on the date of the First Commercial Sale of a Licensed Product and ending on the [***] of such date, Cycleron will pay to Medsteer an annual minimum royalty payment as follows: [***] (“**Annual Minimum Royalty Payment**”). The first Annual Minimum Royalty Payment will be paid within [***] following the First Commercial Sale of a Licensed Product, and thereafter the Annual Minimum Royalty Payment will be payable within [***] following the start of each Calendar Year until the [***] of the First Commercial Sale of a Licensed Product. Each Annual Minimum Royalty Payment is creditable against the royalty payments due to Medsteer pursuant to Section 5.3.2 (Royalties) in any Calendar Year.

5.3.2. Royalties. Subject to the terms of this Agreement, including Section 5.3.3 (Royalty Adjustments), during the applicable Royalty Term, on a Cycleron Product-by-Cycleron Product and country-by-country basis, Cycleron will pay to Medsteer a royalty of [***] on the Net Sales of each Licensed Product in each country in the Territory. The obligation to pay royalties will be imposed only once with respect to the same unit of a Licensed Product.

5.3.3. Royalty Adjustments.

- (a) **Third Party Licenses.** On a Calendar Year-by-Calendar Year basis, following the date on which Cycleron has paid an aggregate of [***] in royalties under Section 5.3 (Royalty Payments) across all Licensed Products with respect to a Calendar Year, Cycleron may deduct from the royalties payable to Medsteer under this Section 5.3 (Royalty Payments) with respect to that Calendar Year [***] of any Blocking Third Party Intellectual Property Costs paid by Cycleron, its Affiliates or Sublicensees with respect to such Calendar Year.
- (b) **Aggregate Limitation on Deductions.** Notwithstanding Section 5.3.3(a) (Third Party Licenses), in no event will the royalties that otherwise would be payable under Section 5.3.3(a) (Third Party Licenses) in connection with the Net Sales of the Licensed Products in a Calendar Quarter be reduced to less than [***] of the applicable Net Sales in such Calendar Quarter as a result of the operation of Section 5.3.3(a) (Third Party Licenses); *provided* that Cycleron will have the right to carry over to subsequent Calendar Quarters any excess reduction pursuant to Section 5.3.3(a) (Third Party Licenses) that Cycleron did not use to offset royalties due to Medsteer in a Calendar Quarter as a result of the foregoing royalty floor until the credit has been fully applied.

5.3.4. Royalty Reports; Payments. In each Calendar Quarter in which royalties are due under this

Agreement, no later than [***] after the end of each Calendar Quarter, Cycleron will provide Medsteer a written report (each, a “**Royalty Report**”), which Royalty Report will set forth: (a) the gross sales and Net Sales (in local currency and United States Dollars) for such Calendar Quarter, and each reduction from gross sales taken in the calculation of Net Sales; (b) the applicable Royalty Rate; and (c) the resulting total royalties for the relevant Calendar Quarter in United States Dollars. Cycleron will make all royalty payments for each Calendar Quarter no later than [***] after the end of each Calendar Quarter.

5.4. Records and Audits.

5.4.1. Books and Records. Each Party will (a) keep, and will cause its Affiliates and Sublicensees to keep, complete, true, and accurate books and records in accordance with its Accounting Standards in relation to this Agreement, including in relation to fees payable under the Collaboration Plan, the number of units of Licensed Product sold or otherwise disposed of, the gross amount billed or invoiced for Licensed Products sold or otherwise disposed of, Net Sales of Licensed Products and the deductions taken in the calculation of Net Sales in sufficient detail to enable amounts owed or payable to the other Party hereunder to be determined; and (b) maintain, and cause its Affiliates and Sublicensees to maintain, such books and records for at least three years following the Calendar Year to which they pertain. Each Party (the “**Auditing Party**”) may, upon written request, cause an internationally-recognized independent “Top Four” accounting firm (the “**Auditor**”), that is reasonably acceptable to the other Party (the “**Audited Party**”) to inspect the relevant records of such Audited Party and its Affiliates and Sublicensees to verify the payments made and amounts reported by the Audited Party and its Affiliates and Sublicensees and the related reports, statements, and books of accounts, as applicable.

5.4.2. Audit Procedure. Before beginning its audit, the Auditor will execute a written agreement by which the Auditor agrees to keep confidential all information reviewed during the audit, which agreement will contain terms of non-disclosure and non-use no less stringent than those set forth in this Agreement. The Auditor will have the right to disclose to the Auditing Party only its conclusions regarding any payments owed under this Agreement. Each Party will, and will cause their Affiliates and Sublicensees to, make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Auditing Party. The records will be reviewed solely to verify the accuracy of the Audited Party’s royalties and other payment obligations and compliance with the financial terms of this Agreement.

5.4.3. Frequency; Overpayments and Underpayments. Such inspection right will not be exercised more than [***]. In addition, the Auditing Party will only be entitled to audit the books and records of the Audited Party or its Affiliates or Sublicensees for the three Calendar Years prior to the Calendar Year in which the audit request is made. The Auditing Party agrees to hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any Applicable Law or judicial order. The Auditor will provide its audit report and basis for any determination to the Audited Party at the time such report is provided to the Auditing Party before it is considered final. In the event that the final result of the inspection reveals an underpayment or overpayment by either Party, the underpaid or overpaid amount will be settled promptly. The Auditing Party will pay for such inspections, as well as its expenses associated with enforcing its rights with respect to any payments hereunder; *provided* that if an underpayment of more than [***] of the total payments due hereunder for the applicable year is discovered, then the fees and expenses charged by the Auditor will be paid by Audited Party.

- 5.5. Currency and Method of Payment.** All amounts to be paid by Cycleron pursuant to this Agreement will be made in United States Dollars. When conversion of payments from any foreign currency is required to be undertaken by Cycleron, the United States Dollar equivalent will be calculated at the exchange rate set forth in *The Wall Street Journal* or any successor thereto for the last day of the Calendar Quarter in which the applicable payment obligation became due and payable. All payments made by Cycleron under this Agreement will be made by bank or wire transfer based on the account information disclosed by Medsteer prior to such payment.
- 5.6. Withholding Taxes.** With respect to any payment under this Agreement (“**Payments**”), the receiving Party alone will be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be paid by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Either Party (a “**Withholding Party**”) may deduct or withhold from the Payments due to the other Party (a “**Non-Withholding Party**”) any Taxes that it is required by Applicable Law to deduct or withhold. If, however, the Non-Withholding Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, then it may deliver to the Withholding Party or the appropriate Governmental Authority (with the assistance of the Withholding Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Withholding Party of its obligation to withhold tax, and the Withholding Party will apply the reduced rate of withholding, or dispense with withholding, as the case may be. If the Withholding Party withholds any Taxes from the Payments while the Non-Withholding Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, then the Withholding Party will cooperate with the Non-Withholding Party with respect to any documentation required by the appropriate Governmental Authority or reasonably requested by the Non-Withholding Party to secure a reduction of the rate of, or the elimination of, the applicable Taxes withheld.

ARTICLE 6 INTELLECTUAL PROPERTY

- 6.1. Background Technology.** As between the Parties, each Party will retain all of its rights, title and interests to all Patent Rights, Know-How and other Intellectual Property Rights that are owned or otherwise controlled by such Party or its Affiliates prior to the Effective Date or are otherwise conceived, discovered, developed, invented, created or otherwise made or acquired by such Party or its Affiliates outside the performance of activities under this Agreement (any such Patent Right with respect to a Party, a “**Background Patent Right**,” such Know-How with respect to a Party, “**Background Know-How**,” and the Background Patent Rights and Background Know-How collectively, “**Background Technology**”), subject to any rights or licenses expressly granted by such Party to the other Party under this Agreement.
- 6.2. Ownership of Program Know-How and Program Patent Rights.**
- 6.2.1. Ownership of Program Know-How.** Subject to the license grants to Medsteer set forth in Section 3.4 (License Grants to Medsteer) and the Medsteer Option set forth in Section 6.2.3 ([***]), the Parties will jointly own all Know-How made solely by either Party, or jointly by the Parties, or by each of their and their Affiliates’ and Sublicensees’ employees, agents, or independent contractors in the course of performing the Collaboration Activities (“**Program Know-How**”). For clarity, Program Know-How does not include any Program Patent Rights.
- 6.2.2. Ownership of Program Patent Rights.** Cycleron will solely own any Patent Rights that claim or

otherwise disclose any Program Know-How (“**Program Patent Rights**”).

6.2.3. Medsteer Option [***]. Cyclerion grants to Medsteer a non-transferable option to [***] (the “**Medsteer Option**”).

- (a) Medsteer may exercise the Medsteer Option by delivering written notice of such exercise (such notice, the “**Medsteer Option Exercise Notice**”) to Cyclerion at any time during the period commencing on the Effective Date and ending on [***] (the “**Medsteer Option Exercise Period**”).
- (b) [***].
- (c) [***].

6.2.4. Cooperation. Subject to Section 6.2.3(b), Medsteer will cooperate fully in obtaining patent and other proprietary protection for any patentable Program Know-How, all in the name of Cyclerion and at Cyclerion’s cost and expense. Such cooperation will include, without limitation, executing and delivering all requested applications, assignments and other documents in order to perfect and enforce Cyclerion’s rights in the Program Know-How. Medsteer hereby appoints Cyclerion its attorney-in-fact to execute and deliver any such documents on behalf of Medsteer if Medsteer fails to do so.

6.2.5. Disclosure.

- (a) **Disclosure of Program Know-How.** During the Collaboration Term, each Party will promptly disclose to the JC all Program Know-How that it develops or invents, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such Program Know-How), including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates’ employees, agents, or independent contractors relating thereto. Each Party will also respond promptly to reasonable requests from the other Party for additional information relating to such Program Know-How.
- (b) **Cyclerion Disclosure of Improvements to Medsteer Background Technology.** During the Collaboration Term, Cyclerion will disclose to Medsteer any improvements made by Cyclerion or its Affiliate to the Medsteer Background Technology that Medsteer has disclosed to Cyclerion (“**Cyclerion Improvements**”). Any such information disclosed by Cyclerion will be deemed Cyclerion’s Confidential Information under this Agreement. Upon Medsteer’s request, the Parties will negotiate in good faith a non-exclusive license grant from Cyclerion to Medsteer under the Cyclerion Improvements for use in the Medsteer Field on commercially reasonable terms.

6.2.6. Personnel Obligations. Each employee, agent, or independent contractor of a Party or its respective Affiliates or Sublicensees performing work under this Agreement will, prior to commencing such work, be bound by invention assignment obligations, including: (a) promptly reporting any invention, discovery, process or other Intellectual Property Rights; (b) presently assigning to the applicable Party all of her or his rights, title and interests in and to any invention, discovery, process, or other Intellectual Property Rights; (c) cooperating in the prosecution and maintenance and enforcement of any patent and patent application; and (d) performing all acts and signing, executing, acknowledging, and delivering any and all documents required for effecting the

obligations and purposes of this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement.

6.3. Patent Enforcement.

6.3.1. Notification. From and after the License Effective Date, each Party will promptly notify the other in the event of any actual, likely, or suspected infringement of any Medsteer Background Patent Right [***] (an “**Infringement**”), including any Competitive Infringement. In addition, from and after the License Effective Date, each Party will promptly notify the other in the event such Party becomes aware of any action by a Third Party for a declaration that any of such Patent Rights are not infringed or are invalid, or unenforceable. In all cases, each Party will provide any available evidence of such Infringement or other conduct with such notification.

6.3.2. Competitive Infringements.

- (a) From and after the License Effective Date, Cycleron will have the first right, but not the obligation, to initiate an infringement or other appropriate suit (an “**Infringement Action**”) against any Competitive Infringement with respect to any Medsteer Background Patent Rights [***] at Cycleron’s discretion and at Cycleron’s sole cost and expense.
- (b) From and after the License Effective Date, if Cycleron fails to initiate an Infringement Action against any Competitive Infringement with respect to any Medsteer Background Patent Right [***] within [***] after written notice of such Competitive Infringement is first provided by a Party under Section 6.3.1 (Notification), then, unless Cycleron has informed Medsteer in writing of a commercial strategic reason for not pursuing such Infringement Action, Medsteer will have the right to initiate and control an Infringement Action with respect to such Competitive Infringement using counsel of its own choice, at its own discretion and at Medsteer’s cost and expense and Cycleron will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

6.3.3. Cooperation. Each Party will provide to the enforcing Party reasonable assistance in the enforcement action brought under this Section 6.3 (Patent Enforcement), at such enforcing Party’s request and expense, including to be named in such action if required by Applicable Law to pursue such action. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts, will reasonably consider the other Party’s comments on any such efforts, including determination of litigation strategy, filing of material papers to the competent court. With respect to any enforcement action brought under this Section 6.3 (Patent Enforcement) brought after the License Effective Date, the non-enforcing Party will be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party. After the License Effective Date, the enforcing Party will not settle any claim, suit, or action that it brought under Section 6.3.2 (Competitive Infringement) in any manner that would limit the rights of the other Party or impose any obligation on the other Party, without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned, or delayed.

6.3.4. Expenses and Recoveries. The enforcing Party bringing a claim, suit, or action under Section 6.3.2 (Competitive Infringement) will be solely responsible for any expenses (including attorneys’ fees and costs) incurred by such Party as a result of such claim, suit, or action. If such Party recovers

monetary damages in such claim, suit, or action commenced after the License Effective Date, then such recovery will be allocated first to the reimbursement of any expenses incurred by the Party bringing suit, second to the reimbursement of any expenses incurred by the other Party in such litigation, [***].

- 6.4. Defense of Claims.** From and after the License Effective Date, each Party will promptly inform the other Party in writing if such Party receives written notice, or otherwise becomes aware, of alleged infringement, misappropriation, or other violation of a Third Party's Intellectual Property Right based upon such Party's performance of its obligations or exercise of its rights hereunder. Except as otherwise set forth under this Agreement (including under Article 9 (Indemnification; Insurance)), such Party will be solely responsible for the defense of any such claim brought against it. After the License Effective Date, such Party will each keep the other Party advised of all material developments in the conduct of any proceedings in defending any claim of alleged infringement, misappropriation or other violation related to any Licensed Products and will reasonably cooperate with the other Party in the conduct of such defense. In no event after the License Effective Date may such Party settle any such infringement, misappropriation, or other violation claim in a manner that would materially limit the rights of the other Party or impose any material obligation on the other Party, in each case, without the other Party's prior written consent, which consent will not be unreasonably withheld, delayed, or conditioned.

ARTICLE 7 CONFIDENTIALITY

7.1. Confidential Information.

- 7.1.1. General.** Each Party (the "**Receiving Party**") will maintain all Confidential Information disclosed to it or its representatives by or on behalf the other Party (the "**Disclosing Party**") in strict confidence during the Term of this Agreement and for a period of ten years after the expiration or termination of this Agreement; *provided* that any Confidential Information of either Party that constitutes a trade secret will continue to be subject to the terms of this Article 7 (Confidentiality) in perpetuity, so long as such information remains a trade secret. Each Party will use all such disclosed Confidential Information only to the extent necessary for purposes of this Agreement, including exercising the licenses and rights hereunder and will not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except as permitted under this Agreement. Each Party will notify the other Party promptly on discovery of any unauthorized use or disclosure by a Party of the other Party's Confidential Information, including the other Party's trade secrets.

- 7.1.2. Confidential Information of Each Party.** All information disclosed prior to the Effective Date by Medsteer to Cycleron will be Confidential Information of Medsteer and by Cycleron to Medsteer will be Confidential Information of Cycleron. All Royalty Reports and reports identifying Milestone Events will be considered Confidential Information of Cycleron. The non-disclosed terms of this Agreement will be the Confidential Information of each Party. The Medsteer Background Know-How will be the Confidential Information of Medsteer, the Cycleron Background Know-How will be the Confidential Information of Cycleron, and the Program Know-How will be the Confidential Information of both Parties, with each Party considered a Receiving Party with respect thereto.

- 7.1.3. Exceptions to Confidentiality.** The following information will not be Confidential Information of the Disclosing Party and accordingly, the obligations of each Receiving Party imposed by Section

7.1.1 (General) will not apply to any such information that: (a) was known to the Receiving Party without an obligation to keep such information confidential prior to the Effective Date other than as a result of disclosure under any other agreement between the Parties, including the Confidentiality Agreement (as demonstrated by documentary evidence); (b) is or becomes generally available to the public through means other than an unauthorized disclosure by the Receiving Party, its Affiliates, or any agents to whom it or they disclosed such information; (c) was or subsequently is disclosed to the Receiving Party without restriction by a Third Party having a *bona fide* right to disclose such Confidential Information without breaching any obligation to the Disclosing Party; or (d) is developed independently by the Receiving Party without benefit of or recourse to any of the Disclosing Party's Confidential Information (as demonstrated by documentary evidence). For clarity, (i) specific aspects or details of Confidential Information will 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; and (ii) any combination of Confidential Information will 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.

7.1.4. Permitted Disclosures.

- (a) **Compliance with Law.** Notwithstanding any provision to the contrary set forth in this Article 7 (Confidentiality), each Receiving Party may use and make disclosures of Confidential Information of the Disclosing Party: (i) to its Affiliates, and the Receiving Party's employees, directors, agents, or consultants to the extent necessary for the potential or actual performance of its obligations or exercise of its licenses and other rights under this Agreement, in each case, who are under an obligation of confidentiality and non-use with respect to such information that is no less stringent than the terms of this Agreement; (ii) to Regulatory Authorities as necessary to pursue Development or Commercialization of Licensed Products; *provided*, that such Confidential Information will be disclosed only to the extent reasonably necessary to do so, and where permitted, subject to confidential treatment; (iii) to Third Parties to the extent a Party is required to do so pursuant to the terms of a Third Party License; *provided* that such Confidential Information will be disclosed only to the extent reasonably necessary to do so under such Third Party License; (iv) to the extent required to comply with Applicable Law or a court or administrative order, including of the United States Securities and Exchange Commission or similar regulatory agency in other countries; (v) to actual or *bona fide* potential investors, acquirors, Sublicensees, lenders, and other financial or commercial partners (including in connection with any royalty financing transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, sublicense, debt transaction, or collaboration; *provided* that, in each such case, such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 7 (Confidentiality) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed, or (vi) to any tax authority, in each case, to the extent applicable to such Party at such time; *provided, however*, that the Party who is required to make such disclosure under the foregoing clauses (ii), (iv), or (vi) (A) provides the

other Party with reasonable prior written notice, (B) coordinates with the other Party with respect to the wording and timing of any such disclosure and affords the other Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure, (C) if unsuccessful in its efforts pursuant to clause (B), takes all reasonable and lawful actions to obtain confidential treatment for such disclosure, and (D) discloses the minimum amount and scope of the Confidential Information necessary to comply with Applicable Law. Notwithstanding the foregoing, any Confidential Information so disclosed will remain subject to the terms of this Agreement.

- (b) **SEC Filings and Other Disclosures.** If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or a similar regulatory agency in a country other than the United States, such Party will (i) a reasonable time prior to any such filing, provide the other Party with a copy of the Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, (ii) provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and (iii) take such Party's reasonable comments into consideration before filing such Agreement and, unless impermissible upon the advice of such Party's counsel, have terms identified by such other Party afforded confidential treatment by the applicable regulatory agency.

7.2. No Use of Name. Except as set forth in this Section 7.2 (No Use of Name), neither Party will use the name or Trademarks of the other Party in any promotional materials or advertising without the prior written consent of the other Party, except as provided under this Agreement or required by Applicable Law, in which case the Party disclosing such name or Trademarks will give advance notice of such use and otherwise comply with Section 7.1.4(a) (Compliance with Law). Notwithstanding the foregoing, Medsteer consents to the use by Cycleron of Medsteer's Trademarks, name and likeness in written materials and oral presentations to current or prospective customers, partners, investors or others, provided that such materials or presentations accurately describe the nature of Medsteer's relationship with or contribution to Cycleron.

7.3. Publication and Publicity.

7.3.1. Publication. Except for disclosures permitted pursuant to Section 7.1.4 (Permitted Disclosures), neither Party will publicly present or publish the results of, or scientific information regarding any activities under this Agreement for the Licensed Products after the License Effective Date. If either Party desires to publicly present or publish the results of, or scientific information regarding, any activities under this Agreement in accordance with the foregoing sentences, then prior to doing so, such Party will provide the other Party with drafts of proposed abstracts, manuscripts, or summaries of presentations that include such results or information. The non-publishing Party will respond no later than [***] after receipt of such proposed publication or presentation or such shorter period as may be agreed by the Parties. The publishing Party will delay any such proposed publication or presentation for a reasonable period (not to exceed [***] after the non-publishing Party receives such proposed publication or presentation) to permit the non-publishing Party to make filings for patent protection and will otherwise remove Confidential Information of the non-publishing Party identified by the non-publishing Party in such publication or presentation. Each Party agrees to acknowledge the contributions of the other Party and the other Party's employees, in each case, in all publications and in accordance with standard academic practice regarding authorship of scientific publication.

- 7.3.2. Publicity.** Subject to Section 7.1.4 (Permitted Disclosures) or except as otherwise agreed by the Parties in writing, neither Party will make any press release or other public statement disclosing this Agreement, or the activities hereunder, or the transactions contemplated by this Agreement, without the other Party's prior written consent.

**ARTICLE 8
REPRESENTATIONS, WARRANTIES, AND COVENANTS**

- 8.1. Mutual Representations and Warranties.** As of the Effective Date and the License Effective Date, Medsteer and Cycleron each hereby represents and warrants to the other as follows:
- 8.1.1. Organization.** It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.
- 8.1.2. Authorization.** The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party's certificate of incorporation or bylaws (or equivalent charter or organizational documents), (b) any agreement, instrument or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law or regulations or court or administrative under, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or Governmental Authority presently in effect applicable to such Party.
- 8.1.3. No Inconsistent Obligation.** It is not under any obligation, contractual, or otherwise, to any Person that conflicts with or is inconsistent in any respect with the terms of this Agreement or that will impede the diligent and complete fulfillment of its obligations hereunder.
- 8.1.4. No Conflicts.** The execution, delivery and performance of this Agreement by such Party does not conflict with such Party's charter documents, bylaws or other organizational documents, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate Applicable Law or any order, writ, decree, judgment, injunction, determination, or award of any Governmental Authority having jurisdiction over it.
- 8.1.5. No Litigation.** There is no action or proceeding pending or, to such Party, threatened that could reasonably be expected to impair or delay the ability of such Party to perform its obligations under this Agreement.
- 8.1.6. Government Authorizations.** All consents, approvals, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement, including the grant of any licenses, have been obtained.
- 8.1.7. Debarment.** Neither such Party, nor any Affiliate of such Party, has been debarred by any Regulatory Authority, is under investigation for debarment action by any Regulatory Authority, has been disqualified as an investigator pursuant to 21 C.F.R. §312.70, has a disqualification hearing pending or is currently employing or using any Person that has been so debarred or disqualified by any Regulatory Authority to perform any of such Party's obligations under this Agreement.
- 8.2. Additional Representations of Medsteer as of the Effective Date.** As of the Effective Date and the License Effective Date, Medsteer further represents and warrants to Cycleron, that:

- 8.2.1. Medsteer Inventions and Assignments.** With respect to any Medsteer Background Know-How, (a) Medsteer and its Affiliates have obtained from all individuals who contributed to the conception or reduction to practice thereof, effective assignments of all ownership rights of such individuals in such Medsteer Background Know-How, either pursuant to written agreement or by operation of law, and (b) all of its employees, officers, and consultants have executed agreements or have existing obligations under Applicable Law requiring assignment to Medsteer or its Affiliates or designees (including Cycleron), as applicable, of all Program Know-How made during the course of performance under this Agreement.
- 8.2.2. No Medsteer Infringement.** To the knowledge of Medsteer, (a) there is no pending action or proceeding alleging that the use of the Medsteer Background Technology with respect to the Cycleron Products infringes, misappropriates, or otherwise violates any Intellectual Property Rights of any Third Party, and, (b) there is no pending action or proceeding alleging that the use of the Medsteer Background Technology as otherwise contemplated under this Agreement infringes, misappropriates, or otherwise violates any Intellectual Property Rights of any Third Party.
- 8.2.3. Medsteer In-License Agreements.** Except for the Medsteer In-License Agreements, there is no agreement between Medsteer or any of its Affiliates and any Third Party pursuant to which Medsteer or its Affiliate has acquired Control of any of the Medsteer Background Technology. All Medsteer In-License Agreements are in full force and effect and have not been modified or amended. Neither Medsteer nor its Affiliates nor, to the best of its knowledge, the Third Party licensor in any Medsteer In-License Agreement is in material breach of, or in default with respect to a material obligation under, any Medsteer In-License Agreement, and neither such party has claimed or has grounds upon which to claim that the other party is in material breach of, or in default with respect to a material obligation under, any Medsteer In-License Agreement.
- 8.3. Compliance Covenants.** Each of Cycleron and Medsteer covenant to the other as follows:
- 8.3.1. Compliance with Law.** It will, and will ensure that its Affiliates, comply with all Applicable Law in connection with the performance of its and its Affiliates' activities under this Agreement, including, to the extent applicable, the U.S. Foreign Corrupt Practices Act, the European Data Protection Directive 95/46/EC, the European General Data Protection Regulation (Regulation (EU) 2016/679), and any other applicable national data protection legislation.
- 8.3.2. No Inconsistent Obligations.** It will not, and will ensure that its Affiliates will not, take any action or enter into any agreement with any Third Party that conflicts with or in any way diminishes the rights granted to the other Party under this Agreement.
- 8.3.3. Medsteer In-License Agreements.** Medsteer will promptly notify Cycleron in writing of any material breach by Medsteer or its Affiliate or a Third Party of any Medsteer In-License Agreements, and will promptly notify Cycleron in writing if Medsteer or its Affiliate sends or receives a notice of material breach of any Medsteer In-License Agreements, and in the event of a breach by Medsteer or its Affiliate, will permit Cycleron to cure such breach on Medsteer's or its Affiliate's behalf upon Cycleron's request. Medsteer will not, and will cause its Affiliates not to, amend, modify or terminate any Medsteer In-License Agreement in a manner that would adversely affect Cycleron's rights hereunder without first obtaining Cycleron's written consent, which consent may be withheld in Cycleron's sole discretion.
- 8.3.4. Foreign Corrupt Practices Act of 1977.** In performing under this Agreement, it will, and will cause its Affiliates and Sublicensees to, comply with all applicable anti-corruption laws, including

the Foreign Corrupt Practices Act of 1977, as amended from time-to-time; the anti-corruption laws of the Territory and all laws enacted to implement the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

- 8.3.5. No Bribery.** It will not, and will cause its Affiliates and Sublicensees not to, directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence: (a) any elected or appointed government official (*e.g.*, a member of a ministry of health); (b) any employee or person acting for or on behalf of a Governmental Authority; (c) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) an employee or person acting for or on behalf of a public international organization; or (e) any person otherwise categorized as a government official under local law.
- 8.3.6. Export Control.** Neither it nor its Affiliates will export, transfer, or sell any Licensed Product to any country or territory except in compliance with Applicable Law.
- 8.4. Medsteer Compliance Covenants.** Medsteer covenants to Cycleron as follows:
- 8.4.1. No Encumbrances.** Medsteer will not, and will cause its Affiliates not to (a) license, sell, assign or otherwise transfer to any Person any Medsteer Background Technology (or agree to do any of the foregoing), (b) negotiate with, offer to, or grant any license to any Person, or (c) incur or permit to exist, with respect to any Medsteer Background Technology, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness), in each case ((a) through (c)), that would conflict with, limit, impair or restrict the rights and licenses granted to Cycleron hereunder or would cause any Medsteer Background Technology to cease to be Controlled by either Medsteer or a successor-in-interest of Medsteer in connection with an assignment permitted under Section 11.4 (Assignability and Binding Effect).
- 8.4.2. Debarment.** It will not, and will cause its Affiliates and Sublicensees not to, engage, in any capacity in connection with this Agreement or any ancillary agreements, any officer, employee, contractor, consultant, agent, representative, or other person who has been debarred by any Regulatory Authority, is under investigation for debarment action by any Regulatory Authority, has been disqualified as an investigator pursuant to 21 C.F.R. §312.70, has a disqualification hearing pending or is currently employing or using any Person that has been so debarred or disqualified by any Regulatory Authority to perform any of such Party's obligations under this Agreement. Medsteer will inform Cycleron in writing promptly if it or any person engaged by it or any of its Affiliates who is performing any obligations under this Agreement or any ancillary agreements is debarred or excluded, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Medsteer's knowledge, is threatened, pursuant to which Medsteer, any of its Affiliates or any such person performing obligations hereunder or thereunder may become debarred or excluded.

ARTICLE 9 INDEMNIFICATION

- 9.1. Indemnification by Cycleron.** Subject to Section 9.3 (Indemnification Procedure), Cycleron will defend, indemnify, and hold harmless Medsteer and its Affiliates, and their respective employees, officers, and directors ("**Medsteer Indemnitees**") from and against any and all liability, damage,

loss, cost or expense of any nature (including reasonable attorney's fees and litigation expenses) ("**Losses**") incurred or imposed upon the Medsteer Indemnitees or any one of them in connection with any Third Party claims, suits, actions, demands, proceedings, causes of action, or judgments resulting from a Third Party claim arising out of or relating to: [***].

- 9.2. Indemnification by Medsteer.** Subject to Section 9.3 (Indemnification Procedure), Medsteer will defend, indemnify, and hold harmless Cycleron and its Affiliates, Sublicensees, and licensees, and their respective employees, officers and directors ("**Cycleron Indemnitees**") from and against any and all Losses incurred or imposed upon the Cycleron Indemnitees or any one of them in connection with any Third Party claims, suits, actions, demands, proceedings, causes of action, or judgments resulting from a Third Party claim arising out of or relating to: [***].
- 9.3. Indemnification Procedure.** Any Person seeking indemnification (the "**Indemnitee**") under this Article 9 (Indemnification; Insurance) will give prompt written notice of the indemnity claim to the indemnifying Party and promptly provide a copy to the indemnifying Party of any complaint, summons, or other written or verbal notice that the Indemnitee receives in connection with any such claim. An Indemnitee's failure to deliver written notice will relieve the indemnifying Party of liability to the Indemnitee under this Article 9 (Indemnification; Insurance) only to the extent such delay is prejudicial to the indemnifying Party's ability to defend or settle such claim. The indemnifying Party will have the right to assume and control the defense of the indemnification claim at its own expense with counsel selected by the indemnifying Party and reasonably acceptable to the Indemnitee; *provided, however,* that an Indemnitee will have the right to retain its own counsel, with the fees and expenses to be paid by the indemnifying Party, if representation of such Indemnitee by the counsel retained by the indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceedings. The indemnifying Party will act reasonably and in good faith with respect to all matters relating to such claim. If the indemnifying Party does not assume the defense of the indemnification claim as described in this Section 9.3 (Indemnification Procedure), then the Indemnitee may defend the indemnification claim but will have no obligation to do so. The Indemnitee will not settle or compromise the indemnification claim without the prior written consent of the indemnifying Party, and the indemnifying Party will not settle or compromise the indemnification claim in any manner that would have an adverse effect on the Indemnitee's interests (including any rights under this Agreement or the scope, validity, or enforceability of any Patent Rights, Confidential Information, or other rights licensed to Cycleron by Medsteer hereunder), without the prior written consent of the Indemnitee, which consent, in each case (by the indemnifying Party or the Indemnitee, as the case may be), will not be unreasonably withheld, conditioned, or delayed. The Indemnitee will reasonably cooperate with the indemnifying Party at the indemnifying Party's expense and will make available to the indemnifying Party all pertinent information under the control of the Indemnitee, which information will be subject to Article 7 (Confidentiality). The indemnifying Party will not be liable for any settlement or other disposition of the claims by the Indemnitee if such settlement is reached without the written consent of the indemnifying Party pursuant to this Section 9.3 (Indemnification Procedure).
- 9.4. Cooperation.** The non-controlling Party will cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party), including, at the controlling Party's sole cost and expense, (a) providing access to relevant documents and other evidence, (b) using reasonable efforts to make its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants, and agents available during reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (c) if reasonably necessary, by being joined as a party, subject for this clause (c) to the controlling Party

agreeing to pay those costs incurred by such non-controlling Party in connection with such joinder. The Party controlling any such action will keep the other Party reasonably updated with respect to any such action, including providing copies of all materials documents received or filed in connection with any such action.

9.5. Limited Liability. [***].

**ARTICLE 10
TERM AND TERMINATION**

10.1. Term. This Agreement will commence on the Effective Date and, unless otherwise terminated pursuant to Section 10.2 (Termination), will continue until the earlier of (a) if Cyclerion has not exercised the Cyclerion Option, upon the expiration of the Cyclerion Option Exercise Period, and (b) if Cyclerion has exercised the Cyclerion Option, upon the expiration of all payment obligations set forth hereunder with respect to all Licensed Products in each country in the Territory (the “**Term**”). Upon the expiration of this Agreement following the License Effective Date (if such License Effective Date occurs) all licenses granted to Cyclerion under this Agreement will become fully paid, perpetual and irrevocable.

10.2. Termination. This Agreement may be terminated as follows:

10.2.1. Termination for Convenience by Cyclerion. Cyclerion may terminate this Agreement at will, in its entirety, on not less than [***] prior written notice to Medsteer.

10.2.2. Termination for Material Breach. This Agreement may be terminated by either Party (the “**Non-Breaching Party**”) in its entirety, in accordance with the terms of this Section 10.2.2 (Termination for Material Breach), if the other Party (the “**Alleged Breaching Party**”) has materially breached this Agreement. The Non-Breaching Party may terminate this Agreement upon written notice to the Alleged Breaching Party at any time during the Term upon or after a material breach of this Agreement by the Alleged Breaching Party if the Alleged Breaching Party has not cured such breach within [***] (in the case of a breach of a payment obligation) or [***] (in the case of all other breaches) following receipt of written notice from the Non-Breaching Party requesting cure of the breach; *provided, however*, that any right to terminate under this Section 10.2.2 (Termination for Material Breach) will be stayed and the cure period tolled in the event that, during any cure period, the Alleged Breaching Party will have initiated dispute resolution in good faith in accordance with the terms of this Agreement with respect to the alleged breach, *provided* that the Alleged Breaching Party gives written notice to the Non-Breaching Party of such dispute during the applicable cure period. If, as a result of such dispute resolution process, it is finally determined that the Alleged Breaching Party committed a material breach of this Agreement then the applicable cure period will resume and if the Alleged Breaching Party does not cure such material breach within the remainder of such cure period, 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.

10.2.3. Termination for Insolvency. If a Party (the “**Insolvent Party**”) makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [***] after the filing thereof (each, an “**Insolvency Event**”), the other Party may terminate this Agreement in its entirety by providing written notice

of its intent to terminate this Agreement to the Insolvent Party, in which case, this Agreement will terminate on the date on which the Insolvent Party receives such written notice.

- 10.3. Effects of Termination.** In the event of any termination of this Agreement, effective as of the effective date of termination, the following provisions will apply, as applicable:
- 10.3.1. Termination of Rights and Licenses.** Subject to Section 10.4 (Surviving Provisions), except as expressly set forth in this Agreement, all options, rights, and licenses granted from one Party to the other hereunder will immediately terminate.
- 10.3.2. Confidential Information.** Upon termination of this Agreement for any reason, the Receiving Party will destroy all written, electronic, or other materials containing Confidential Information of the Disclosing Party provided to it by the Disclosing Party in connection with this Agreement, including all copies thereof, within [***] of such termination and provide certification of such destruction to the Disclosing Party; *provided* that (a) the Receiving Party may retain one copy in its archives solely for the purpose of monitoring its ongoing confidentiality obligations hereunder, and (b) the Receiving Party will not be obligated to destroy such materials containing Confidential Information of the Disclosing Party that are necessary for the Receiving Party to exercise any other license or right of the Receiving Party that survives such termination of this Agreement; *provided* that the Receiving Party's use of such Confidential Information of the Disclosing Party will continue to be subject to the requirements and restrictions set forth in Article 7 (Confidentiality).
- 10.4. Surviving Provisions.** Subject to the other terms and conditions regarding the termination and survival of obligations under this Agreement in the event of expiration or termination of this Agreement, upon expiration or termination of this Agreement, all provisions of this Agreement will cease to have any effect, except that the following provisions will survive any such expiration or termination for any reason for the period of time specified therein, or if not specified, then they will survive indefinitely: Article 1 (Definitions), Section 2.1.2 (Fees), Section 2.1.4 (Cyclerion Materials), Section 3.11 (Non-Solicitation) (for the period set forth therein), Section 3.12 (Right of First Negotiation), Section 4.3 (Medsteer Background Software Escrow), Section 5.4 (Records and Audits), Section 5.5 (Currency and Method of Payment), Section 5.6 (Withholding Taxes), Article 6 (Intellectual Property), Article 7 (Confidentiality) (for the period set forth therein), Section 9 (Indemnification), Section 10.3 (Effects of Termination), this Section 10.4 (Surviving Provisions), and Article 11 (Miscellaneous).

ARTICLE 11 MISCELLANEOUS

- 11.1. Independent Contractor.** All Collaboration Activities performed by Medsteer will be performed as an independent contractor and this Agreement does not create an employer-employee relationship between Cyclerion and Medsteer. Medsteer will have no rights to receive any employee benefits, such as health and accident insurance, sick leave or vacation which are accorded to regular Cyclerion employees. Medsteer will not in any way represent himself to be an employee, partner, joint venturer, or agent of Cyclerion.
- 11.2. Interpretation.** The Parties acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party will not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement will be construed fairly as to each Party and not in a favor of or against either Party,

regardless of which Party was generally responsible for the preparation of this Agreement. In addition, except as otherwise explicitly specified to the contrary, (i) references to a section, schedule or exhibit means a section of, or schedule or exhibit to this Agreement, unless another agreement is specified, (ii) the word “including” (in its various forms) means “including without limitation,” (iii) the words “shall” and “will” have the same meaning, (iv) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulations, in each case as amended or otherwise modified from time-to-time, (v) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires, (vi) references to a particular Person include such Person’s successors and assigns to the extent not prohibited by this Agreement, (vii) references to “days” will mean calendar days, unless otherwise specified, (viii) the word “or” will not be exclusive, unless the context otherwise requires, (ix) references to “written” or “in writing” include in electronic form, (x) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement, and (xi) the terms “hereof,” “hereby,” “hereto,” and derivative or similar words refer to this entire Agreement, including any schedules or exhibits hereto.

- 11.3. Further Assurances.** Each of Cycleron and Medsteer agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, the filing of such 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.
- 11.4. Assignability and Binding Effect.** The Collaboration Activities to be performed by Medsteer are personal in nature. Medsteer may not assign or transfer this Agreement or any of Medsteer’s rights or obligations hereunder except (a) to a corporation of which Medsteer is the sole stockholder, (b) to its successor in interest in the transfer or sale of all or substantially all of its assets or business to which this Agreement relates, or (c) to its successor in interest in a merger or consolidation (or similar transaction). In no event will Medsteer assign or delegate responsibility for actual performance of the Collaboration Activities assigned to it under the Collaboration Plan to any other natural person. This Agreement will be binding upon and inure to the benefit of the Parties and their respective legal representatives, heirs, successors and permitted assigns.
- 11.5. Notices.** All notices required or permitted under this Agreement must be in writing and must be given by addressing the notice to the address for the recipient set forth in this Agreement or at such other address as the recipient may specify in writing under this procedure. Notices will be deemed to have been given (a) three (3) Business Days after deposit in the mail with proper postage for first class registered or certified mail prepaid, or (b) one (1) Business Day after sending by nationally recognized overnight delivery service.

Notices to Cycleron:

Cycleron Therapeutics, Inc.
245 First Street, Riverview II, 18th Floor
Cambridge, MA 02142, U.S.A
Attention: Legal Department

Notices to Medsteer:

Medsteer, SAS
Hopital Foch, Service Anesthesie, 40 Rue Worth, 92151
Suresnes, France
Attention: Thierry Chazot, MD, CEO
Email: [***]

- 11.6. No Modification.** This Agreement may be changed only by a writing signed by Medsteer and an authorized representative of Cycleron.
- 11.7. Remedies.** It is understood and agreed that each Party may be irreparably injured by a breach of this Agreement; that money damages would not be an adequate remedy for any such breach; and that each Party will be entitled to seek equitable relief, including injunctive relief and specific performance, without having to post a bond, as a remedy for any such breach, and such remedy will not be such Party's exclusive remedy for any breach of this Agreement.
- 11.8. Severability; Reformation.** Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction will be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof and without affecting the validity or enforceability of any of the other terms of this Agreement in such jurisdiction, or the terms of this Agreement in any other jurisdiction. The Parties will substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible to the original intent of the Parties.
- 11.9. Waiver.** No waiver of any term, provision or condition of this Agreement in any one or more instances will be deemed to be or construed as a further or continuing waiver of any other term, provision or condition of this Agreement. Any such waiver must be evidenced by an instrument in writing executed by Medsteer or, in the case of Cycleron, by an officer authorized to execute waivers.
- 11.10. Entire Agreement.** This Agreement constitutes the entire agreement of the parties with regard to its subject matter, and supersedes all previous written or oral agreements, representations, agreements and understandings between the parties on the subject matter, including the Consulting Agreement.
- 11.11. Termination of Consulting Agreement.** As of the Effective Date, the Consulting Agreement is hereby terminated in its entirety and all provisions therein are superseded by this Agreement.
- 11.12. Governing Law.** This Agreement will be governed by, construed, and interpreted in accordance with the laws of the Commonwealth of Massachusetts, without reference to principles of conflicts of laws. The Parties further agree that the venue of any action, injunctive application or dispute determinable by a court of law arising out of this Agreement or any order shall be the County of Suffolk, Commonwealth of Massachusetts, and that the federal and state courts therein shall have jurisdiction over the subject matter and the parties.
- 11.13. Counterparts.** This Agreement may be executed simultaneously in any number of counterparts by digital or telephonic facsimile transmission (including PDF), each of which will be an original and both of which, together, will constitute a single agreement.
- 11.14. Headings.** The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

MEDSTEER SAS

CYCLERION THERAPEUTICS, INC.

By: /s/ Thierry Chazot

By: /s/ Regina Graul

Name: Thierry Chazot

Name: Regina Graul

Title: President

Title: CEO

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Schedule 1.75
Medsteer Background Know-How

[***]

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Schedule 1.76
Medsteer Background Patent Rights

[***]

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Schedule 2.1.1
Collaboration Plan

[***]

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Schedule 3.8
Medsteer In-License Agreements

[***]

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CYCLERION THERAPEUTICS, INC.
INSIDER TRADING PREVENTION POLICY
JULY 3, 2019

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1.0 Policy

The purpose of this policy is to reduce the potential for risk of violating U.S. securities laws by the directors, officers, other employees, and consultants of Cycleron Therapeutics, Inc. (the “Company”) as well as the potential for such risk by the members of their immediate families who share the same household as the director, officer, employee, or consultant (“Immediate Family”).

2.0 Scope

This policy applies to all Cycleron directors, officers, employees, consultants and their Immediate Family. Directors, officers, employees, and consultants are responsible for informing their Immediate Family of, and ensuring their compliance with, their obligations under this policy. This policy is referenced in the Cycleron Code of Business Conduct and Ethics.

3.0 General Prohibitions

Generally speaking, U.S. securities laws prohibit the buying or selling of securities based on inside information as defined by applicable laws. The Company seeks to comply with such laws and therefore prohibits any employee, officer, director or consultant to the Company from buying or selling common stock or other securities of the Company (including debentures, bonds and notes), or directing trades of any securities of the Company, while that individual is aware of material, nonpublic information relating to the Company. The Company also prohibits any employee, officer, director, or consultant to the Company from communicating such “material nonpublic information” to someone else who then acts on it by buying or selling the Company’s securities (known as “tipping”). This policy also applies to material nonpublic information about any other company with whom the Company is negotiating or does business. You may not trade in the securities of any company on the basis of such information, nor may you communicate information about any such company to others. Furthermore, the same restrictions apply to your Immediate Family and, therefore, you are also responsible for their compliance with this policy.

On a related point, no one should discuss the Company’s material nonpublic information in public areas—such as corridors, airplanes and restaurants—and care should be taken in the handling and disposal of company information, in whatever form or media (papers, computer drives, etc.) containing material nonpublic information.

The Company has adopted this policy in response to the law and also to avoid even the appearance of improper conduct by anyone associated with the Company. We strive to establish our Company’s reputation for integrity and ethical conduct and cannot afford to have it damaged.

In all cases, the responsibility for determining whether an individual is in possession of material nonpublic information rests with that individual, and any action on the part of the Company, the General Counsel (or his or her designee) or any other employee or director pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. Individuals may be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this policy or applicable securities laws, as described below in more detail under the heading “Consequences of Violating this Policy.”

4.0 Key Terms

4.1 Insider

Any person who possesses material nonpublic information is considered an insider as to that information. Insiders include the Company’s directors, officers, employees, independent contractors and those persons in a special relationship with the Company, e.g., its auditors, consultants, or attorneys. The definition of insider is transaction specific; that is, an individual is an insider with respect to each material nonpublic item of which he or she is aware.

4.2 Material Information

Information is “material” if a reasonable investor would consider it significant in a decision to buy, hold, or sell securities. Put another way, information that could reasonably be expected to affect the price of a security, either positively or negatively, is material.

Common examples of information that will frequently be regarded as material is information relating to:

- prescription results and trends, as well as the associated revenues, for any of the Company’s marketed products;
-

- clinical trial results for any product candidates in the Company’s pipeline;
- significant discoveries, or significant developments with regard to the Company’s existing products candidates;
- negotiations or other significant developments regarding an important license, distribution agreement, joint venture, collaboration or other contract material to the Company’s business;
- pending FDA or other regulatory action;
- financial results that are significantly higher or lower than generally expected by the investment community;
- a pending or proposed merger, acquisition, sale of part of the Company’s business or acquisition of another business;
- impending securities offerings by the Company;
- a proposed stock split or stock dividend;
- changes in management, the Board of Directors or other major changes in personnel;
- major litigation developments;
- impending financial problems; and
- other changes in the status of any of the Company’s activities which may have an adverse or favorable impact.

Other types of information may also be material; no complete list can be given.

4.3 Nonpublic

Information is “nonpublic” or “inside information” until such time that it has been made available to investors generally and the market has had time to digest it. As a general matter, Cycleron considers two (2) business days to be a sufficient period for new information to be absorbed and evaluated by the market.

Whether a particular item is “material” or “nonpublic” will be judged with the benefit of hindsight. Accordingly, when in doubt as to a particular item of information, you should presume it to be material and not to have been disclosed to the public. Do not hesitate to contact Cycleron’s General Counsel or Chief Financial Officer with any questions on this.

5.0 Timing of Transactions

5.1 General Rule

If you know of material nonpublic information about the Company, you should not engage in any securities transactions before the completion of two (2) full trading days following when the information is publicly announced in a press release or in a report filed by the Company with the Securities and Exchange Commission (SEC). If, however, the information relates to the Company’s financial performance, you should wait until the completion of one (1) full trading day after the earlier of (i) the issuance of the Company’s quarterly investor update, or (ii) filing by the Company of its annual report or quarterly report with the SEC. This will typically occur during February or March, May, August, and November. There are no exceptions to the above limitations, even for transactions that may be claimed to be justifiable for independent reasons (such as the need to raise money for an emergency expenditure).

5.2 Blackout Periods

It is a violation of this policy for directors, “officers” (as defined in Section 16 of the Securities Exchange Act of 1934, as amended), and other persons who, because they are in a position to routinely become aware of material nonpublic information, are periodically designated by the General Counsel or Chief Financial Officer as being subject to these additional procedures to make any transaction in the market (purchase or sale) during a “blackout period” that covers the period from the last business day of each calendar quarter (i.e., March, June, September and December) until the completion of one (1) full trading day following the investor update. In addition, the General Counsel, Chief Financial Officer, or their designees may put in place issue- specific additional blackout periods on a case-by- case basis. If you are named to an issue- specific blackout list, you will be notified by the General Counsel, Chief Financial Officer or their designees and shall remain

subject to the prohibition against trading until such time that the General Counsel, Chief Financial Officer or their designees notifies you that the blackout has been lifted.

5.3 Pre-Clearance

Each director and “officer” (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) must contact the General Counsel, Chief Financial Officer or their designees at least forty-eight (48) hours prior to making any transaction (e.g., purchase, sale or gift) involving the Company’s securities to obtain pre-clearance of such transaction. The brokers employed by a director or such officer may be required to sign an acknowledgement of the foregoing. If clearance to engage in a trade is received, you must complete the proposed trade within two (2) trading days or make a new trading request.

If the Company is in a blackout period, or you are otherwise in possession of material nonpublic information, you may be asked to postpone your transaction until the blackout period is lifted or you otherwise receive permission to trade from the General Counsel, Chief Financial Officer or their designees. The General Counsel and Chief Financial Officer are under no obligation to approve a transaction submitted for pre-clearance. If you seek pre-clearance and permission to engage in the transaction is denied, then you should refrain from initiating any transaction in Company securities, and should not inform any other person of the restriction.

Any transaction in Company securities by a director or “officer” (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) must be reported to the General Counsel or his or her designee on the same day in which the transaction occurs. Compliance with this provision is imperative given the requirement of Section 16 of the Securities Exchange Act of 1934, as amended, that directors and “officers” (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) generally must report changes in ownership of Company securities to the Securities and Exchange Commission within two (2) business days. Each report should include the date of the transaction, quantity of securities, price and broker-dealer through which the transaction was effected, in addition to any other information requested by the Company from time to time.

5.4 Post-Termination Transactions

This policy continues to apply to transactions in Company securities even after an individual has terminated employment or other services to the Company or a subsidiary as follows:

- If the individual is aware of material nonpublic information when the employment or service relationship terminates, he or she shall pre-clear any transaction (purchase or sale) of Company securities in the market with the General Counsel, Chief Financial Officer or their designee until the earlier of (i) six (6) months following termination and (ii) the date that the information has become public; and
- If the individual is subject to a blackout when the employment or service relationship terminates, he or she may continue to be subject to such blackout until notified by the General Counsel, Chief Financial Officer, or their designee.

6.0 Stock Options, Restricted Stock Units and Employee Stock Purchase Plan Shares

The restrictions set forth herein do not apply to exercises of stock options in which an employee purchases shares of Cycleron stock pursuant to such stock options; such option exercises do not require prior approval. Any sales of shares purchased pursuant to stock options, however, are subject to the restrictions set forth in this policy. In particular, some “cashless exercises” include both exercises of options and an immediate sale of stock acquired via the option exercise; therefore, “cashless exercises” which include a sale of securities are subject to the restrictions set forth herein.

Similarly, the restrictions set forth herein do not apply to the issuance of shares from the

Company to an employee upon the vesting of restricted stock units (“RSUs”) or similar rewards. Any sales of such shares, however, are subject to the restrictions set forth in this policy. This includes sales of shares by the Company to satisfy the employee’s tax obligations in connection with the vesting of RSUs; however, if you have properly entered into a Company-administered planned sale program (as described below in more detail under the heading “Planned Sales Programs”) for such sales, such sales will comply with this policy.

Finally, although purchases of Cycleron stock pursuant to the Cycleron Employee Stock Purchase Plan are not subject to the restrictions set forth herein, all sales of shares purchased pursuant to such plan are subject to all the restrictions set forth in this policy.

7.0 Planned Sale Programs

The above limitations do not apply to stock transactions done in accordance with what are commonly known as a “10b5-1 Plan” or “Planned Sale Program”, which were established (or amended as the case may be) at a time when you were not aware of material nonpublic information and in compliance with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended. A 10b5-1 Plan is a document that sets forth a plan to sell securities in the future without any further investment decision(s) at the time of the actual trade consummation. Any 10b5-1 Plan must provide for a waiting period of at least fourteen (14) days prior to the commencement of trading thereunder, and should be reviewed and cleared by the General Counsel, Chief Financial Officer or their designees (including any amendments thereto) in advance of finalizing the 10b-5-1 Plan.

8.0 Special and Prohibited Transactions

There is a heightened legal risk and the appearance of improper or inappropriate conduct if directors or “officers” (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) engage in certain types of transactions. Therefore, these individuals may not engage in any of the following transactions:

- Short sales. Short sales of Company securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company’s prospects. In addition, short sales may reduce a seller’s incentive to seek to improve the Company’s performance. For these reasons, short sales of Company securities are prohibited.
- Publicly-traded options. Given the relatively short term nature of publicly-traded options, transactions in options may create the appearance that a director or officer is trading based on material nonpublic information and focus such person’s attention on short-term performance at the expense of the Company’s long-term objectives. Accordingly, transactions in put options, call options or other derivative securities, on an exchange or in any other organized market, are prohibited by this policy.
- Hedging transactions. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a director or officer to continue to own Company securities obtained through employee equity incentive plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director or officer may no longer have the same objectives as the Company’s other shareholders, and therefore they are prohibited from engaging in any such transactions.
- Margin Accounts and Pledges. Securities held in a margin account or pledged as collateral for a loan may be sold without consent by the broker if an individual fails to meet a margin call or by the lender in foreclosure if an individual defaults on the loan. Because a margin or foreclosure sale that occurs when an individual is aware of material nonpublic information or otherwise is not permitted to trade in Company securities would violate this policy, directors and “officers” (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) are prohibited from holding Company securities in a margin account or pledging Company securities as collateral for a loan. An exception may be granted where an individual wishes to pledge Company securities as collateral for a loan and clearly demonstrates the financial capacity to repay the loan without resorting to the pledged securities. If any such individual wishes to pledge Company securities as collateral for a loan, he or she must submit a request to the General Counsel or his or her designee prior to the proposed execution of documents evidencing the proposed pledge.

9.0 Consequences of Violating this Policy

9.1 The Law

U.S. laws impose heavy penalties on those who, in violation of law, either buy or sell securities while aware of material nonpublic information or pass the material nonpublic information along to others who use it to buy or sell securities. Potential punishments include a range of civil and criminal penalties, as well as the potential for imprisonment.

9.2 Company Sanctions

In view of the seriousness of this matter, the Company will discipline any person who violates this policy by any appropriate means, including dismissal for cause. Any of these consequences and even an investigation that does not result in prosecution, can tarnish your reputation, and irreparably damage you and the Company.

10.0 Company Assistance & Waivers

Anyone with questions about specific transactions may obtain additional guidance from the General Counsel or Chief Financial Officer. Please contact the General Counsel or Chief Financial Officer if you believe that a waiver under a provision of this policy is warranted.

The General Counsel or Chief Financial Officer must obtain the approval of the Chief Executive Officer to grant a waiver hereunder in certain limited circumstances. In addition, a majority of the independent directors or the Audit Committee of the Board of Directors must approve a waiver for any director.

11.0 Revision History

Revision Number	Effective Date	Supersedes	Reason for Revision

12.0 Attachments

None

13.0 Sponsorship and Policy Management

General Counsel and Chief Financial Officer

List of Registrant's Subsidiaries

Cyclerion Securities Corporation, incorporated in Massachusetts, a wholly owned subsidiary.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-257145) of Cycleron Therapeutics, Inc. and the related Prospectus,
- (2) Registration Statement (Form S-3 No. 333-284690) of Cycleron Therapeutics, Inc. and the related Prospectus,
- (3) Registration Statement (Form S-3 No. 333-242334) of Cycleron Therapeutics, Inc. and the related Prospectus,
- (4) Registration Statement (Form S-3 No. 333-287006) of Cycleron Therapeutics, Inc. and the related Prospectus.
- (5) Registration Statement (Form S-8 No. 333-248957) pertaining to 2019 Equity Incentive Plan, 2019 Employee Stock Purchase of Cycleron Therapeutics, Inc.,
- (6) Registration Statement (Form S-8 No. 333-258316) pertaining to 2019 Equity Incentive Plan, 2019 Employee Stock Purchase of Cycleron Therapeutics, Inc.,
- (7) Registration Statement (Form S-8 No. 333-230615) pertaining to 2019 Equity Incentive Plan, 2019 Employee Stock Purchase Plan, Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan, and Amended and Restated 2005 Stock Incentive Plan of Cycleron Therapeutics, Inc.;
- (8) Registration Statement (Form S-8 No. 333-266739) pertaining to 2019 Equity Incentive Plan, 2019 Employee Stock Purchase of Cycleron Therapeutics, Inc.,
- (9) Registration Statement (Form S-8 No. 333-273530) pertaining to 2019 Equity Incentive Plan, 2019 Employee Stock Purchase of Cycleron Therapeutics, Inc.

of our report dated March 30, 2026, with respect to the consolidated financial statements of Cycleron Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 30, 2026

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

I, Regina Graul, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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: March 30, 2026

By: /s/ Regina Graul

Name: Regina Graul

Title: President and Chief Executive Officer (Principal Executive Officer)

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

I, Rhonda Chicko, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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: March 30, 2026

By: /s/ Rhonda Chicko

Name: Rhonda Chicko

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

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

I, Regina Graul, 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 Annual Report on Form 10-K of Cycleron Therapeutics, Inc. for the period ended December 31, 2025 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-K fairly presents, in all material respects, the financial condition and results of operations of Cycleron Therapeutics, Inc.

Date: March 30, 2026

By: /s/ Regina Graul

Name: Regina Graul

Title: President and Chief Executive Officer (Principal Executive Officer)

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

I, Rhonda Chicko, 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 Annual Report on Form 10-K of Cycleron Therapeutics, Inc. for the period ended December 31, 2025 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-K fairly presents, in all material respects, the financial condition and results of operations of Cycleron Therapeutics, Inc.

Date: March 30, 2026

By: /s/ Rhonda Chicko

Name: Rhonda Chicko
Title: Chief Financial Officer (Principal Financial and Accounting Officer)
