Cyclerion Announces Corporate Updates and Q1 2023 Financial Results

May 11, 2023

Definitive agreement reached with new company ("NewCo") established by certain Cyclerion shareholders and new investors

Cyclerion to receive $8M in cash and 10% equity in NewCo in exchange for its zagociguat and CY3018 assets

Definitive agreement signing triggers previously announced $5M equity investment in Cyclerion

Cyclerion CEO Peter Hecht Ph.D. to lead NewCo while continuing to serve on the Cyclerion board as one of the company's largest shareholders

Biopharma executive Errol De Souza Ph.D. elected as chair of the Cyclerion board

CAMBRIDGE, Mass., May 11, 2023 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN) today announced corporate updates and first quarter 2023 financial results.

Definitive Agreement Signed

On May 11, 2023 Cyclerion entered into a definitive agreement to sell two of its sGC* stimulator assets, zagociguat (formerly CY6463) and CY3018, to a new private company ("NewCo") formed by certain current Cyclerion shareholders and new investors who have agreed to invest $81M to advance these assets. Under the terms of the agreement, Cyclerion will receive an $8M cash payment at closing, reimbursement for all expenses related to zagociguat and CY3018 for the period between signing and closing of the transaction, and 10% equity ownership in NewCo that is subject to anti-dilution protection through $100M in post-money valuation. Cyclerion will also have additional future equity purchase rights in NewCo. The transaction is subject to approval by Cyclerion shareholders and, once completed, will enable the assets to be developed in NewCo with the capital and capabilities to advance them while giving Cyclerion shareholders the opportunity to participate in future value creation without having the obligation to make direct investments and take on the risk of these early-stage programs.

Go Forward Strategy

Previously, Cyclerion out-licensed the peripherally active sGC stimulator praliciguat to Akebia Therapeutics, Inc. ("Akebia"), a leading biopharmaceutical company focused on kidney disease. Under the terms of that agreement, the Company is eligible to receive up to $585M in development, regulatory, and commercialization milestones, as well as sales-based royalties. Cyclerion retains full rights to olinciguat, an oral, once-daily, peripheral sGC stimulator, that has shown a favorable safety and tolerability profile, drug characteristics, and dose-dependent pharmacological activity in several placebo controlled clinical studies. Olinciguat has a strong patent estate with intellectual property exclusivity to the late 2030s. sGC stimulators are now approved for PAH** and HFrEF*** (both multibillion dollar opportunities). In similar fashion to today's transaction and the Akebia license, Cyclerion intends to identify a partner with deep cardiovascular experience to maximize olinciguat's value while minimizing distraction and operating expense.

These external development deals make up a growing diverse portfolio of upside value for our shareholders and the potential for non-dilutive funds from upfront and milestone payments and/or monetization of equity positions and royalties. The externalization of the initial sGC assets means that Cyclerion now has the opportunity to bring in new assets to develop using its highly efficient and externalized model. The Company will initially target assets in the CNS therapeutic area that are at a later stage of development and can be advanced to approval more quickly.

Upon approval of the current transaction by Cyclerion shareholders, Peter Hecht will transition out of his Cyclerion CEO role and join NewCo as its CEO. Dr. Hecht, a major Cyclerion shareholder, will continue to serve as a Cyclerion Director. Cyclerion has initiated a search to bring in a new leader to drive the company's strategy going forward.

Board of Directors

Current independent board member Errol De Souza has been elected to serve as the chair of the Cyclerion Board effective immediately. Dr. De Souza is a seasoned R&D and business leader with broad experience - from large pharma to start ups - in the discovery and development of therapeutics for the treatment of CNS disorders.

"I am excited to have a unique platform from which to exercise my passion for finding underappreciated and undervalued neuro assets. I've been fortunate to have had multiple successful opportunities to uncover important neuro therapies through approval that are having profound impacts on patients' lives, and I've done so in a variety of circumstances, including small biotechs" said Errol De Souza, Chair of the Cyclerion Board of Directors. "I am looking forward to the opportunity to take learnings from each of those and apply them to Cyclerion alongside a group of supportive, long-term, core investors."

ADv Study Results

Cyclerion recently completed the analysis of its signal-seeking clinical study of zagociguat for the potential treatment of Alzheimer's disease with vascular pathology (ADv) (NCT04798989). This exploratory, randomized, placebo-controlled, study of oral once-daily zagociguat was designed to evaluate safety, tolerability, and pharmacokinetics as well as explore the impact on biomarkers and cognitive performance over a twelve-week dosing period. The total number of participants in the study was capped at 12 participants due to challenges associated with enrollment. Data from this study show that the safety and tolerability profile of once-daily zagociguat was consistent with prior studies. Given the small number of participants Cyclerion is unable to draw any conclusions from the data generated in the study.

Equity Investment

Signing of the definitive agreement today triggered the previously announced $5M equity investment by CEO Peter Hecht. This investment will take place on May 19, 2023 and Hecht will receive a mix of common stock and nonvoting convertible preferred stock of Cyclerion at a minimum purchase price of $0.434 per share, subject to adjustment for any reverse stock split or similar event. The proceeds from this investment and the $8M upfront from the sale of zagociguat and CY3018 are expected to support ongoing operations for at least 12 months post-closing of the transaction.

Financial Position

- Cash, cash equivalents, and restricted cash balance on March 31, 2023 was approximately $7.2 million, as compared to approximately $13.4 million on December 31, 2022.
- Research and development expenses were approximately $3.8 million for Q1 2023, as compared to approximately $9.7 million for Q1 2022. The decrease of approximately $6.0 million was primarily driven by decreases of $3.1 million in external research and development costs related to zagociguat and CY3018, $1.6 million in employee-related expenses, $0.6 million in non-cash stock-based compensation, and $0.6 million in professional services.
- General and administrative expenses were approximately $3.3 million for Q1 2023, as compared to approximately $4.0 million for Q1 2022. The decrease of approximately $0.7 million was primarily driven by a decrease in non-cash stock-based compensation.
- Net Loss: Net loss was approximately $7.0 million for Q1 2023, as compared to approximately $13.0 million for Q1 2022.

About Cyclerion Therapeutics

Cyclerion Therapeutics is a clinical-stage biopharmaceutical company on a mission to develop treatments for serious diseases. Cyclerion's portfolio includes novel sGC stimulators that modulate a key node in a fundamental signaling network in both the CNS and the periphery. The multidimensional pharmacology elicited by the stimulation of sGC has the potential to impact a broad range of diseases. 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. CY3018 is a CNS-targeted sGC stimulator in preclinical development that preferentially localizes to the brain and has a pharmacology profile that suggests its potential for the treatment of neuropsychiatric diseases and disorders. Praliciguat is a systemic sGC stimulator that is licensed to Akebia and being advanced in rare kidney disease. Olinciguat is a vascular sGC stimulator that the Company intends to out-license for cardiovascular diseases. For more information about Cyclerion, please visit https://www.cyclerion.com/ and follow us on Twitter (@Cyclerion) and LinkedIn (www.linkedin.com/company/cyclerion).

Forward Looking Statement

Certain matters discussed in this press release are "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should", "positive" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding the assessment of the best combination of capital, capabilities, and transactions available to it resulting in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms, the success of any such potential transactions in delivering any future value to the Company, the sufficiency of any expected revenues to provide liquidity and capital resources to pursue any of our go-forward business plans regarding any product candidate, the potential for zagociguat in the treatment of mitochondrial diseases, the potential for CY3018 in the treatment of CNS diseases, the potential for olinciguat in the treatment of cardiovascular and cardiopulmonary diseases, the potential for any successful development of any of our assets, and other trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success of any transactions in delivering any future value to the company, our ability to succeed with any go-forward business, the sufficiency of any expected proceeds to provide liquidity and capital resources to pursue any of our go-forward business plans regarding any product candidate (including without limitation our ability to fund additional clinical trials); any ability to successfully demonstrate the efficacy, safety and therapeutic effectiveness of any product candidate; any results of clinical studies not necessarily being indicative of or supported by the final results of subsequent clinical trials; the timing of and ability to pursue, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, product candidates; the Company's ability to successfully defend its intellectual property or obtain necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's license agreements; the acceptance by the market of the product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

* sGC (Soluble guanylate cyclase)

** PAH (Pulmonary arterial hypertension)

*** HFrEF (Heart failure with reduced ejection fraction)

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