



Cybin Announces Additional Strategic Clinical Site Partnerships to Support PARADIGM, a Multinational Phase 3 Program Evaluating CYB003

April 23, 2025

- Strategic Partnership Agreements promote collaboration and aligned incentives across sites, enhancing operational efficiency and improving site performance and patient recruitment -

- Phase 2 data confirmed that two 16 mg doses of CYB003 administered three weeks apart provides remission from depression symptoms for 12 months in 71% of MDD patients -

- Patient dosing continues in APPROACH, Cybin's first pivotal Phase 3 study of CYB003 for the adjunctive treatment for Major Depressive Disorder ("MDD") -

- Second Phase 3 study, EMBRACE, is expected to begin mid-2025 -

TORONTO--(BUSINESS WIRE)-- [Cybin Inc.](#) (NYSE American:CYBN) (Cboe CA:CYBN) ("**Cybin**" or the "**Company**"), a clinical-stage breakthrough neuropsychiatry platform company committed to revolutionizing mental healthcare by developing new and innovative next-generation treatment options, today announced additional strategic partnership agreements ("SPAs"), bringing the total to 18 clinical sites engaged to advance Cybin's multinational Phase 3 program evaluating CYB003 for the adjunctive treatment of MDD. The APPROACH study is expected to include approximately 45 clinical sites.

"This SPA model serves to take advantage of the deep expertise of each individual site and ensure that protocols and best practices are shared consistently," said Doug Drysdale, Chief Executive Officer of Cybin. "This level of cooperation will streamline trial operations and has the potential to reduce time to completion. We are especially pleased that Kimball A. Johnson, M.D., Medical Director of CenExel iResearch Atlanta, who served as the principal investigator for our successful Phase 1/2a CYB003 trial, and Paul Thielking, Chief Scientific Officer, Cedar Clinical Research, are participating in the SPA program. Our SPA partners are experienced in neuropsychiatric drug trials and share Cybin's deep commitment to the highest quality standards of investigational clinical work, and to developing safe and effective next-generation treatments to improve patient outcomes."

"I am delighted that iResearch Atlanta is participating in this next exciting stage of development for CYB003, and that we will be part of a consortium of sites working to advance its Phase 3 program," said Kimball A. Johnson, M.D., Medical Director of CenExel iResearch Atlanta.

"Cedar Clinical Research has extensive experience in this space, and we are eager to join the other sites supporting Cybin's PARADIGM program and address the global crisis in mental health," said Paul Thielking, Chief Scientific Officer, Cedar Clinical Research, a Numinus Wellness Inc. company.

Cybin initiated the SPA program earlier this year with Segal Trials, a leading clinical research network located in South Florida. Each of the 18 U.S.-based SPA sites bring decades of clinical experience and a commitment to excellence to support and expedite the Company's Phase 3 PARADIGM program.

About Cybin

Cybin is a late-stage breakthrough neuropsychiatry company committed to revolutionizing mental healthcare by developing new and innovative next-generation treatment options to address the large unmet need for people who suffer from mental health conditions.

With industry leading proof-of-concept data, Cybin is working to change the mental health treatment landscape through the introduction of intermittent treatments that provide long lasting results. The Company is currently developing CYB003, a proprietary deuterated psilocin program, in Phase 3 development for the adjunctive treatment of major depressive disorder and CYB004, a proprietary deuterated N, N-dimethyltryptamine program in a Phase 2 study for generalized anxiety disorder. The company also has a research pipeline of investigational, 5-HT-receptor focused compounds.

Founded in 2019, Cybin is operational in Canada, the United States, the United Kingdom, the Netherlands and Ireland. For Company updates and to learn more about Cybin, visit www.cybin.com or follow the team on X, LinkedIn, YouTube and Instagram.

Cautionary Notes and Forward-Looking Statements

Certain statements in this news release relating to the Company are forward-looking statements and are prospective in nature.

Forward-looking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as “may”, “should”, “could”, “intend”, “estimate”, “plan”, “anticipate”, “expect”, “believe” or “continue”, or the negative thereof or similar variations. Forward-looking statements in this news release include statements regarding the Company’s plans to enroll patients across clinical sites in the United States and Europe; the potential reduction in drug development timeline afforded by its SPA program; the eventual inclusion of approximately 45 clinical sites; and the Company’s plans to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health disorders.

These forward-looking statements are based on reasonable assumptions and estimates of management of the Company at the time such statements were made. Actual future results may differ materially as forward-looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results, performance, or achievements of the Company to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors, among other things, include: implications of the spread of a pandemic on the Company’s operations; fluctuations in general macroeconomic conditions; fluctuations in securities markets; expectations regarding the size of the psychedelics market; the ability of the Company to successfully achieve its business objectives; plans for growth; political, social and environmental uncertainties; employee relations; the presence of laws and regulations that may impose restrictions in the markets where the Company operates; and the risk factors set out in each of the Company’s management’s discussion and analysis for the three and nine month periods ended December 31, 2024 and the Company’s annual information form for the year ended March 31, 2024, which are available under the Company’s profile on SEDAR+ www.sedarplus.ca and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Although the forward-looking statements contained in this news release are based upon what management of the Company believes, or believed at the time, to be reasonable assumptions, the Company cannot assure shareholders that actual results will be consistent with such forward-looking statements, as there may be other factors that cause results not to be as anticipated, estimated or intended. Readers should not place undue reliance on the forward-looking statements and information contained in this news release. The Company assumes no obligation to update the forward-looking statements of beliefs, opinions, projections, or other factors, should they change, except as required by law.

Cybin makes no medical, treatment or health benefit claims about Cybin’s proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding psilocin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of psilocin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds can diagnose, treat, cure or prevent any disease or condition. Rigorous scientific research and clinical trials are needed. If Cybin cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on Cybin’s performance and operations.

Neither the Cboe Canada nor the NYSE American LLC stock exchange have approved or disapproved the contents of this news release and are not responsible for the adequacy and accuracy of the contents herein.

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