



Cybin Engages Thermo Fisher Scientific to Provide U.S.-Based Manufacturing for its CYB003 Program for the Adjunctive Treatment of Major Depressive Disorder

May 15, 2025

- Thermo Fisher Scientific, the world leader in serving science, is providing Phase 3 capsule clinical supply and will support future commercial manufacturing efforts for CYB003 -

- Production of both drug substance and drug product will be performed at Thermo Fisher's U.S. pharma services manufacturing sites -

TORONTO--(BUSINESS WIRE)-- [Cybin Inc.](#) (NYSE American:CYBN) (Cboe CA:CYBN) ("**Cybin**" or the "**Company**"), a clinical-stage breakthrough neuropsychiatry company committed to revolutionizing mental healthcare by developing new and innovative next-generation treatment options, today announced that it has engaged Thermo Fisher Scientific ("Thermo Fisher"), the world leader in serving science, to support the Phase 3 clinical supply and potential commercial manufacturing of CYB003, the Company's proprietary deuterated psilocin program in Phase 3 development for the adjunctive treatment of Major Depressive Disorder ("MDD").

"This is an exciting time for Cybin as we focus on the execution of our Phase 3 CYB003 pivotal program," said Doug Drysdale, Chief Executive Officer of Cybin. "Thermo Fisher, which offers leading Contract Development and Manufacturing Organization (CDMO) services, has a successful track record across the manufacturing spectrum, and their expertise will help to accelerate our drug development trajectory. We are pleased to broaden our existing strong relationship with Thermo Fisher for both the drug substance and drug product capsules for CYB003. Cybin has established its manufacturing operations in the United States, including partnering with Thermo Fisher's pharma services sites in Florence, South Carolina, for Phase 3 clinical supply and future commercialization, and Cincinnati, Ohio, for Phase 3 capsule production and commercialization."

"Affiliating with a world-class manufacturing partner is critical for us as we advance this important program and address a significant unmet medical need in the treatment of mental health disorders," said Aaron Bartlone, Chief Operating Officer of Cybin.

Vincent Hingot, President Drug Substance, Pharma Services, at Thermo Fisher added, "We are proud to partner with Cybin on their groundbreaking CYB003 program. Our collaboration underscores our commitment to leveraging our advanced manufacturing capabilities to support innovative treatments that address significant unmet medical needs in mental health."

In March 2024, CYB003 received U.S. Food and Drug Administration ("FDA") Breakthrough Therapy Designation. Among its many benefits, this designation provides an expedited review pathway and the potential to accelerate drug development timelines. It also includes all "fast track" program features and acknowledges the significant unmet medical need for more effective treatments of MDD.

The Company's Phase 2 study results of CYB003 in MDD showed remarkable efficacy at 12 months, including a 100% response rate and a 71% remission rate among participants who received two 16 mg doses. Based on the strength of the Phase 2 study results, Cybin initiated PARADIGM™, its multinational pivotal Phase 3 program evaluating CYB003 in a broader population of MDD patients, in November 2024.

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 analog, in Phase 3 studies for the adjunctive treatment of major depressive disorder and CYB004, a proprietary deuterated N, N-dimethyltryptamine molecule 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", "potential", "possible", "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 commercial manufacturing of CYB003; the potential for FDA Breakthrough Therapy Designation to accelerate drug development timelines; and the Company's plans to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health conditions.

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: 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; implications of disease outbreaks on the Company's operations; and the risk factors set out in each of the Company's management's discussion and analysis for the three and nine months 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+ at 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 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 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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