Cybin Completes Enrollment in Phase 2 Study Evaluating CYB004 for the Treatment of Generalized Anxiety Disorder

September 8, 2025

- The Phase 2 GAD study has enrolled 36 participants to evaluate the safety and efficacy of CYB004 at 12 weeks after first dose -

- Reaffirms top-line data guidance for Q1 2026 -

TORONTO--(BUSINESS WIRE)--Sep. 8, 2025-- Cybin Inc. (NYSE American:CYBN) (Cboe CA:CYBN) ("**Cybin**" or the "**Company**"), a clinical-stage breakthrough neuropsychiatry company committed to advancing mental healthcare by developing new and innovative next-generation treatment options, today announced completion of enrollment in its Phase 2 study evaluating CYB004, a proprietary deuterated dimethyltryptamine ("DMT") program, for the treatment of Generalized Anxiety Disorder ("GAD") and reaffirms top line data guidance expected in the first quarter of 2026.

"Completing enrollment in our Phase 2 study of CYB004 marks a significant milestone on our path to bringing forth an effective treatment for GAD," said Eric So, Interim Chief Executive Officer of Cybin. "Improved treatments are greatly needed, as anxiety disorders affect more than 300 million people worldwide. GAD is the most common anxiety disorder seen in primary care, with roughly 6.8 million people living with GAD in the United States alone. Unfortunately, half of these patients do not respond to approved treatment with selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors. We are excited about CYB004, and its potential to offer convenient intramuscular dosing for patients in need. We are proud of this work to date, as well as the robust patent protection in support of our CYB004 program, and we look forward to sharing topline data in the first quarter of 2026."

About the Phase 2 CYB004 Study in GAD

- The CYB004-002 Phase 2 study is a randomized, double-blind study evaluating the safety and efficacy of CYB004 in participants with moderate to severe GAD (GAD-7 score ≥10) and are currently taking concomitant antidepressant or anxiolytic treatments. Participants with co-morbid depression are allowed.
- The study is evaluating safety and efficacy at 12 weeks, with an optional follow-up to assess efficacy at 12 months. The study will remain double-blinded through Week 12.
- The study has enrolled 36 participants, who were randomized into two groups (randomized 2:1).
- The first group received two intramuscular administrations of CYB004 three weeks apart at a dose predicted to be therapeutic (20 mg CYB004), while the second group received two intramuscular administrations of CYB004 three weeks apart at a lower dose predicted to be sub-therapeutic (2 mg CYB004).
- The primary endpoint is a change in the HAM-A ("Hamilton Anxiety Rating Scale") score from baseline at six weeks following the first administration of CYB004.
- Secondary endpoints include change in HAM-A through the double-blind period (Week 12).
- Other endpoints include the HAM-D (Hamilton Depression Rating Scale), safety assessments, MEQ30 (psychedelic experience assessment) and EQ-5D-5L (quality of life assessment).

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 promising class leading proof-of-concept data, Cybin is working to change the mental health treatment landscape through the introduction of novel drugs that provide effective and durable results for patients. The Company is currently developing CYB003, a proprietary deuterated psilocin analog, in Phase 3 studies for the adjunctive treatment of major depressive disorder that has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration 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, 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 or forward-looking information

within the meaning of applicable securities laws (collectively, “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 Company’s plans to share CYB004 topline data in the first quarter of 2026; potential for CYB004 to provide convenient intramuscular dosing 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 months ended June 30, 2025 and the Company’s annual information form for the year ended March 31, 2025, 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/edgar. 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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