# Cybin Provides Corporate Update on Upcoming Clinical Milestones

September 19, 2024

*- Initiation of pivotal CYB003 Phase 3 study in Major Depressive Disorder (“MDD”) expected imminently -*

*- 12-month efficacy data from Phase 2 study of CYB003 in MDD expected in early Q4 2024 -*

*- Phase 2 topline efficacy and safety results for CYB004 in Generalized Anxiety Disorder (“GAD”) expected year-end 2024 or early Q1 2025 -*

*- Strengthened R&D team with addition of experienced drug development leaders Dr. Atul R. Mahableshwarkar, and Dr. Tom Macek, as program leads for CYB003 and CYB004, respectively -*

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 reported recent clinical accomplishments and key upcoming clinical milestones.

“We are making rapid advancements in our two lead clinical programs – CYB003, our proprietary deuterated psilocin program in development for the adjunctive treatment of Major Depressive Disorder and CYB004, our proprietary deuterated dimethyltryptamine program for the treatment of Generalized Anxiety Disorder. We have made significant progress in preparing for our upcoming Phase 3 programs and have appointed two experienced drug development experts, Dr. Atul R. Mahableshwarkar, and Dr. Tom Macek, to lead our CYB003 and CYB004 programs, respectively. As we evolve into a Phase 3 Company, we are well positioned among the top tier in our sector and believe that we have the potential to deliver innovative, next-generation approaches to address these challenging mental health disorders,” said Doug Drysdale, Chief Executive Officer of Cybin.

**CYB003: A proprietary deuterated psilocin program with FDA Breakthrough Therapy Designation for the adjunctive treatment of MDD**

CYB003 is the Company’s lead program that is preparing to enter Phase 3 development and has received FDA Breakthrough Therapy Designation (“BTD”), which validates CYB003's potential for significant clinical improvements over existing treatments based on preliminary results and serves to expedite CYB003’s development pathway towards commercialization.

In August 2024, the Company held a productive Type B Initial Breakthrough Therapy Meeting with the U.S. Food and Drug Administration (“FDA”) in preparation for the imminent commencement of its CYB003 pivotal program in MDD. For the upcoming Phase 3 study, Cybin has selected 30 high quality clinical sites across the United States and Europe. The Phase 3 pivotal trial design incorporates several elements to address critical methodological issues such as functional unblinding that are considered important for drugs in this class.

To date, results from a completed Phase 2 MDD study of CYB003 have shown rapid, robust improvements in symptoms of depression with a single dose, and durable effects four months after two doses with a 75% remission rate in the 16mg dose group. The Company expects to report 12-month Phase 2 efficacy data in early Q4 2024, providing further insights into CYB003’s potential to provide long-lasting relief for MDD patients.

**Positive Phase 2 Results for CYB003 in MDD**

- Rapid and large improvements in symptoms of depression after single doses with average 13.75 point difference in MADRS score reduction between CYB003 (12mg and 16mg pooled) and placebo at 3 weeks ($p<0.0001$)
- Incremental benefit of second dose with >75% response rates and up to 80% remission rates (12 mg) after second dose
- Efficacy sustained at 4 months after 2 doses, with a mean 22-point reduction in MADRS scores from baseline and robust remission rates of 60% (12 mg) and 75% (16 mg)
- Excellent safety and tolerability profile, with all reported AEs mild to moderate

**CYB004: A proprietary deuterated N,N-dimethyltryptamine (“DMT”) program in development for the treatment of GAD**

CYB004 is being developed as a highly scalable intermittent treatment with an intramuscular (“IM”) formulation designed to optimize the delivery of CYB004, with acute effects lasting approximately 90 minutes. Dosing is underway in a Phase 2 study of IM CYB004 in participants with moderate to severe GAD. The Phase 2 results are expected to provide proof-of-concept for CYB004’s efficacy in GAD, time to onset of effects, and durability of effects to one year. The Company plans to report topline

safety and efficacy results at year-end 2024 or early Q1 2025.

**CYB004 Phase 2 Program Outline**

- Randomized, double-blind study in 36 participants with moderate to severe GAD (GAD-7 score ≥10) with concomitant antidepressant/anxiolytic treatment and co-morbid depression allowed
- Two IM doses, three weeks apart vs. two low-dose controls
- Primary endpoint is change in Hamilton Anxiety Rating Scale ("HAM-A") score from baseline at 6 weeks following second dose
- Other endpoints include the Montgomery-Asberg Depression Rating scale depression assessment, safety assessments, MEQ30 (psychedelic experience assessment) and EQ-5D-5L (quality of life assessment)
- Participants will be followed up initially for a period of three months, with additional follow-up assessments up to a year

**Strengthened research and development team with two key additions:**

- **Dr. Atul R. Mahableshwarkar M.D., DLFAPA, Senior Vice President, Clinical Development.** Dr. Mahableshwarkar is leading the CYB003 program, Cybin's proprietary deuterated psilocin program in development for the adjunctive treatment of MDD. Dr. Mahableshwarkar is a board-certified psychiatrist and accomplished drug development executive with experience in both large global and small startup companies. He brings varied experiences from academia and industry as a site principal investigator for industry-sponsored studies and has submitted several INDs and NDAs leading to drug approvals.
- **Dr. Tom Macek, Pharm.D., Ph.D., Senior Vice President, Clinical Development.** Dr. Macek is leading the CYB004 program, Cybin's proprietary deuterated dimethyltryptamine program in development for the treatment of GAD. Dr. Macek brings decades of pharmaceutical industry experience in new drug development across all phases of research (pre-IND to post-approval) across diverse treatment modalities and has submitted or supported several INDs and NDAs/BLAs leading to drug approvals.

**About Cybin**

Cybin is a clinical-stage breakthrough neuropsychiatry company on a mission to create safe and effective next-generation therapeutics to address the large unmet need for new and innovative treatment options for people who suffer from mental health conditions.

Cybin's goal of revolutionizing mental healthcare is supported by a network of world-class partners and internationally recognized scientists aimed at progressing proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens. Cybin is currently developing CYB003, a proprietary deuterated psilocin program for the treatment of major depressive disorder and CYB004, a proprietary deuterated dimethyltryptamine program for generalized anxiety disorder and has a research pipeline of investigational 5-HT-receptor focused compounds.

Headquartered in Canada and 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 Company 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 plan to initiate a pivotal CYB003 Phase 3 Study imminently; the potential reduction in drug development timeline afforded by BTD; the release of 12-month Phase 2 data for CYB003 in early Q4 2024; the release of Phase 2 topline data for CYB004 in Q4 2024 or early 2025; and the Company's 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 COVID-19 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 months ended June 30, 2024 and the Company's annual information form for the year ended March 31, 2024, which are available under the Company's profile on 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 psilocybin, 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 psilocybin, 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. Cybin has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that Cybin verified such in clinical trials or that Cybin will complete such trials. 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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