# Cybin Reports Positive Phase 2 Data for CYB003, Demonstrating Breakthrough 12-Month Efficacy in Treating Major Depressive Disorder

November 18, 2024

*- 100% of participants were responsive to treatment and 71% of participants were in remission at 12 months after just two 16 mg doses of CYB003 -*

*- Robust, long-term efficacy with ~23-point reduction in Montgomery-Asberg Depression Rating Scale (“* ***MADRS*** *”) score compared to baseline at 12 months after two 16 mg doses of CYB003 -*

*- Findings validate dosing regimen and confirm that CYB003’s effects are highly durable and offer sustained relief for MDD patients -*

*- CYB003 continues to be well-tolerated and demonstrates an excellent safety profile -*

*- Cybin’s Phase 3 PARADIGM* ™ *multinational pivotal program evaluating the efficacy and safety of CYB003 has been initiated -*

*- Company to host conference call and webcast to discuss 12-month Phase 2 CYB003 results today at 8:00 a.m. ET -*

***This news release constitutes a “designated news release” for the purposes of Cybin’s prospectus supplements each dated August 23, 2023 for the Company’s ATM Program, to its short form base shelf prospectus dated August 17, 2023, as amended December 22, 2023 and April 8, 2024.***

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 unprecedented 12-month efficacy data from its Phase 2 study of CYB003, a proprietary deuterated psilocin program in development for the potential adjunctive treatment of major depressive disorder (“ **MDD** ”). As previously announced, CYB003 received Breakthrough Therapy Designation by the U.S Food and Drug Administration (the “ **FDA** ”) for this indication, which provides an expedited review pathway.

“We are highly encouraged that our approach to treating MDD patients with two 16 mg doses of CYB003, three weeks apart, has demonstrated consistent, robust and sustained treatment benefits through to the 12-month follow up. The trajectory of effect is truly remarkable. We previously reported response and remission rates of 75% at four months. By the 12-month mark, response rates improved to 100% while 71% of participants were still in remission. These findings validate our dosing regimen and confirm that CYB003’s effects are highly durable and offer sustained relief,” said Amir Inamdar, MBBS, DNB (Psych), FFPM, Chief Medical Officer of Cybin. “At 12 months, the mean change from baseline in MADRS total score was nearly 23 points for patients who received two 16 mg doses. With such unprecedented response and remission rates and effects that are durable with two doses of CYB003, we have the potential to address a significant unmet need and deliver a truly transformative treatment for patients with MDD.” [1]

“Our Phase 2 study results are remarkable and validate both our intermittent dosing regimen, as well as CYB003’s potential to revolutionize the current standard of care in MDD,” [1] said Doug Drysdale, Chief Executive Officer of Cybin. “We are quite possibly witnessing a watershed moment in mental health care treatment paradigms and practices. [1] Up to two thirds of MDD patients do not achieve remission with first-line antidepressants, which have defined the current treatment standard. With CYB003, we have the opportunity to pivot away from the chronic, daily treatments that often only offer symptomatic relief, and move towards more patient-friendly infrequent, long-lasting therapeutics for MDD patients who do not achieve remission with existing treatments. [1] Current intermittent treatments like esketamine, ECT and TMS require on average up to 36 outpatient visits per treatment cycle, burdening both patients and treatment centers. In comparison, CYB003’s two doses per treatment cycle have the potential to free up capacity for new patients and improve accessibility to treatment. [1] We believe that these landmark results mark a profound and exciting shift as we move away from treating the *symptoms* of the disease to potentially changing the course of the disease.” [1]

**Summary of 12-Month Efficacy Data for CYB003 16 mg**

- Eight participants completed the 12-month follow-up of which seven received two doses (active-active) of 16 mg and one received a single dose of 16 mg (placebo – active).
- Mean change from baseline in MADRS was ~23 points after two doses of 16 mg (n=7).
    - Mean baseline MADRS was 32 points across the 12 mg and 16 mg dosing arms.

- 100% of participants receiving two doses of 16 mg were responders.
- 71% of participants receiving two doses of 16 mg were in remission.
    - The two participants in the 16 mg dosing arm that were responders (≥50% reduction in MADRS score) but not remitters had MADRS scores of 11; remission is defined as MADRS total score ≤10.

**Summary of 12-Month Efficacy Data for CYB003 12 mg**

- Thirteen participants completed the 12-month follow-up of which ten received two doses (active-active) of 12 mg and three received a single dose of 12 mg (placebo – active).
- Mean change from baseline in MADRS was ~18 points after two doses of 12 mg (n=10).
- 60% of participants receiving two doses of 12 mg were responders.
- 50% of participants receiving two doses of 12 mg were in remission.

**Safety and tolerability:**

- CYB003 has demonstrated an excellent safety profile. No new adverse events were reported in the 12-month follow up, including no reports of suicidality.

"As a late-stage neuropsychiatry company, we are nearing several key inflection points across our clinical pipeline. Having aligned on trial design with the FDA, we recently initiated our Phase 3 PARADIGM ™ pivotal program which will evaluate CYB003's efficacy and safety in a larger MDD population, and we expect to report Phase 2 topline results for CYB004, our proprietary deuterated dimethyltryptamine program for the treatment of generalized anxiety disorder, in the first quarter of 2025. [1] We are committed to building on the positive clinical results to-date in both programs and to progressing CYB003 toward potential regulatory approval and commercialization," concluded Drysdale.

**Conference Call and Webcast Details:**

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| Date: | Monday, November 18, 2024 |
| Time: | 8:00 a.m. ET. |
| Dial-in: | 800-579-2543 (U.S. Toll-Free) or 785-424-1789 (International) |
| Conference ID: | CYBN1118 |
| Webcast: | Register for the webcast here |

The archived webcast will also be available on the Company's investor relations website on the Events & Presentations page.

**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.

**Note:**

1. This is a forward-looking statement that involves material assumptions by the Company. Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development and recruitment of patients for participation in clinical trials are dependent on various factors and are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, the number, availability, location and accessibility of clinical trial sites, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.

**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 Company’s potential viability for treatment for patients with MDD and other mental health conditions; the Company’s potential to impact the standard of care in MDD; the Company’s ability to offer different treatment methods; the Company’s ability to improve accessibility to treatment; the potential of CYB003 to change the course of disease; the Company’s plans to report Phase 2 topline results for CYB004 in Q1 2025; 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 six month ended September 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 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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