# Cybin Reports Third Quarter Financial Results and Recent Business Highlights

February 14, 2024

*- Reported positive Phase 2 topline results for CYB003, its proprietary deuterated psilocybin analog in development for the adjunctive treatment of Major Depressive Disorder ("**MDD**"), demonstrating a 79% remission rate from depression -*

*- Announced positive topline results from Phase 1 studies of proprietary deuterated dimethyltryptamine ("**dDMT**") molecules CYB004 and SPL028, supporting clinical advancement and the successful development of an intramuscular ("**IM**") formulation -*

*- Received clearance from U.S. Food and Drug Administration (the "**FDA**") for its investigational new drug (" **IND**") application for CYB004, paving the way for a Phase 2a study in Generalized Anxiety Disorder ("**GAD**") -*

*- Strengthened Intellectual Property ("**IP**") portfolio with more than 50 granted patents and over 170 pending applications -*

TORONTO--(BUSINESS WIRE)-- Cybin Inc. (NYSE American:CYBN) (Cboe CA:CYBN) ("**Cybin**" or the " **Company**"), a clinical-stage biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative next-generation psychedelic treatment options, today reported unaudited financial results for its third quarter ended December 31, 2023, and recent business highlights.

"During the past three months, we have continued to make exciting progress with positive topline data from our CYB003 and DMT programs," said Doug Drysdale, Chief Executive Officer of Cybin. "The data collected from our clinical trials forms the foundation of our next set of value-creating milestones, as we advance our key programs this year. For CYB003, the three-month Phase 2 efficacy data is expected in Q1 and will provide insights into the durability of treatment effect in MDD. Promising outcomes, such as a 79% remission from depression at 6 weeks in our Phase 2 CYB003 trial, and important safety and dosing findings in our Phase 1 dDMT studies, validate our path forward. Plans are underway to initiate a Phase 3 multisite trial of CYB003 for MDD, and with FDA clearance, we are progressing to a Phase 2a study of CYB004 for the treatment of GAD. We are proud of the rapid progress we have made and look forward to the important work ahead of us. We are encouraged by the positive findings across our clinical-stage programs to date and believe we are well on our way to providing more effective and patient-friendly treatment alternatives for a multitude of mental health disorders," concluded Drysdale.

**Recent Business and Pipeline Highlights:**

**Announced positive Phase 2 topline efficacy and safety data for CYB003, the Company's proprietary deuterated psilocybin analog, in MDD.** The study achieved its primary efficacy endpoint with an impressive mean 14-point difference in Montgomery-Asberg Depression Rating Scale ("**MADRS**") score reduction from baseline between CYB003 (12mg) vs. placebo (p=0.0005)[1] at three weeks. At six weeks, incremental MADRS score reductions were seen with 79% of patients in remission from depression after just two 12mg doses of CYB003 -- an improvement that is far superior when compared against approved antidepressants and recently reported data with other psychedelics. Based on these encouraging results, and coupled with the fact that CYB003 is being developed as an adjunctive treatment that does not require candidates to discontinue the use of existing antidepressants, the Company intends to commence an international, multisite Phase 3 trial to further evaluate the safety and efficacy of CYB003 capsules in a larger MDD patient population[2].

**Completed Phase 1 studies of intravenous ("IV") CYB004 and IM and IV SPL028 and reported positive topline safety, pharmacokinetic ("PK") and pharmacodynamic ("PD") data.**

- CYB004 demonstrated robust and rapid onset of psychedelic effects at lower doses compared to native N,N-dimethyltryptamine ("**DMT**"), suggesting potential as a short-acting, scalable treatment.
- Well-tolerated with no serious adverse events, and the majority of adverse events were mild to moderate and self-limiting.
- The study identified an IM dose of SPL028 that resulted in a breakthrough psychedelic experience, with a duration range of 55-120 minutes. IV and IM SPL028 demonstrated a favorable safety and tolerability profile, with no serious adverse events observed. The majority of adverse events were mild to moderate and self-limiting.
- These results support the development of IM dosing, which provides a more convenient and patient-friendly administration route that avoids the need for an IV infusion pump, specialist equipment, staffing and training.
- Combined Phase 1 results from DMT program support progression to a Phase 2a study in GAD in the first quarter of 2024[2].

**Key takeaways from dDMT studies:**

- CYB004 and SPL028 demonstrated similar PK and PD profiles, which allow for synergistic insights that are relevant across

molecules.
- PK profiles for both molecules demonstrated concentrations in the effective range.
- IM dosing of SPL028 produced robust psychedelic effects lasting a short duration in the majority of subjects.

**Received FDA clearance to initiate Phase 2a study of CYB004 in GAD.** The Company intends to initiate a Phase 2a study of CYB004 in the first quarter of 2024[2]. The study will be a randomized, double-blind, active-controlled trial to assess the preliminary clinical efficacy, safety, tolerability, PK, and PD of CYB004 in participants with GAD. This trial will be conducted at study sites in the United States.

**Strengthened patent portfolio with the addition of 6 new patents in key jurisdictions.**

1.The United States Patent and Trademark Office ("**USPTO**") granted U.S. patent 11,834,410 in support of the Company's CYB003 program. The patent includes composition of matter claims to pharmaceutical compositions within Cybin's CYB003 program, as well as claims directed toward the therapeutic treatment of MDD, treatment-resistant depression, and alcohol use disorder, and is expected to provide exclusivity until at least 2041.

2. The USPTO granted U.S. patent 11,771,681 in support of the Company's dDMT program. The patent provides composition of matter protection for certain deuterated analogs of DMT.

3. The USPTO granted U.S. patent 11,773,062 in support of the Company's dDMT program. The patent provides protection for the medical use and the novel, efficient and scalable synthesis of certain analogs of DMT.

4. The Canadian Intellectual Property Office granted CA patent 3,179,161 in support of the Company's dDMT program. The patent provides protection for formulations of certain deuterated analogs of DMT.

5. The Japanese Patent Office granted JP patent 7422473 in support of the Company's dDMT program. The patent provides protection for the novel, efficient and scalable synthesis of certain deuterated analogs of DMT.

6. The Japanese Patent Office granted JP patent 7422474 in support of the Company's dDMT program. The patent provides protection for formulations of certain deuterated analogs of DMT.

**Continued extensive engagement with the scientific community, showcasing advancements in clinical and preclinical programs.** The Company shared four poster presentations at the 2023 American College of Neuropsychopharmacology Annual Meeting, highlighting data from across its CYB003 and dDMT clinical programs, as well as preclinical development programs.

**Upcoming Clinical Milestones and Future Studies:** [2]

**CYB003 - Deuterated Psilocybin Analog Program**

- Phase 2 three-month efficacy data for CYB003 in MDD expected in Q1 2024.
- CYB003 Phase 1/2a data was submitted to the FDA in Q4 2023 to support end of Phase 2 meeting in Q1 2024.
- Initiate a pivotal, international, multisite Phase 3 trial in Q2 2024 to further evaluate the safety and efficacy of CYB003 capsules in a larger MDD patient population.

**dDMT Program**

- Initiate Phase 2a study in participants with generalized anxiety disorder in Q1 2024.

**Third-Quarter Financial Information**

- Cash totaled C$39.0 million as of December 31, 2023.
- With the previously announced public offerings of units of the Company (the "Units") and a combination of the Company's current cash position, current at-the-market equity program and assuming the exercise in full of the warrants issued as part of the Units, the Company has access to over C$121 million.
- Net loss was C$30.3 million for the quarter ended December 31, 2023, compared to a net loss of C$10.7 million in the same period last year.
- Cash-based operating expenses totaled C$17.1 million for the quarter ended December 31, 2023, compared to C$11.1 million, in the prior year quarter.
- Cash flows used in operating activities were C$19.0 million for the quarter ended December 31, 2023, compared to C$10.8 million in the same period last year.
- Cash flows received from financing activities were C$42.4 million for the quarter ended December 31, 2023, compared to C$3.5 million in the same period last year, related to the net proceeds on the issuance of Common Shares through the Company's August 3, 2023 and November 14, 2023 financing and its at-the-market equity program.

**About Cybin**

Cybin is a clinical-stage biopharmaceutical company on a mission to create safe and effective psychedelic-based 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 psilocybin analog for the treatment of major depressive disorder and CYB004, a proprietary dDMT molecule for generalized anxiety disorder and has a research pipeline of investigational psychedelic-based 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 plans to progress to a Phase 3 trial of CYB003 in Q2 2024; initiate a Phase 2a study of CYB004 in Q1 2024; attend an end of Phase 2 meeting with the FDA in Q1 2024; the release of Phase 2 three-month efficacy data for CYB003 in MDD in Q1 2024; the Company's ability to access capital under its current at-the-market offering; the exercise of the warrants issued as part of the Units; 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 month periods ended December 31, 2023 and the Company's annual information form for the year ended March 31, 2023, 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.*

**Notes:**

1. A p-value indicates statistical significance. Values <0.05 are considered statistically significant and values <0.001 are considered highly statistically significant. Cohen's d represents size of the effect. An effect size of 2.15 is considered large.
2. There is no assurance that timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assume 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.

**Investor & Media Contact:**
Gabriel Fahel

Chief Legal Officer
Cybin Inc.
1-866-292-4601
irteam@cybin.com – or – media@cybin.com

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