



Cybin Reports Fiscal Year 2024 Financial Results and Recent Business Highlights

June 26, 2024

- Received U.S. Food and Drug Administration (“FDA”) Breakthrough Therapy Designation (“BTD”) for CYB003, its proprietary deuterated psilocybin analog in development for the adjunctive treatment of Major Depressive Disorder (“MDD”) -

- Clinical site selection complete for Phase 3 multinational study of CYB003, which is expected to begin in summer 2024 -

- Cash totaled C\$209 million as of March 31, 2024 -

- Initiated a Phase 2 study of CYB004, its proprietary deuterated dimethyltryptamine (“DMT”) program in development for the treatment of Generalized Anxiety Disorder (“GAD”) -

- Strengthened intellectual property portfolio with more than 60 granted patents and over 200 pending applications -

- Closed oversubscribed private placement of U.S.\$150 million (the “Private Placement”) led by a syndicate of leading biopharmaceutical institutional investors -

This news release constitutes a “designated news release” for the purposes of Cybin’s prospectus supplements each dated August 23, 2023, 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 biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative next-generation treatment options for mental health disorders, today reported audited financial results for its fiscal year ended March 31, 2024, and recent business highlights.

“I am proud of the swift and meaningful progress we have made advancing our two lead programs – CYB003 for the adjunctive treatment of MDD and CYB004 for the treatment of GAD – this past year. As we stand poised to commence our Phase 3 study of CYB003, Cybin has evolved into a mature, late-stage company with critical milestones on the near-term horizon,” stated Doug Drysdale, Chief Executive Officer of Cybin. “Supported by the BTD from the FDA and positive four-month durability data for our CYB003 program, and the initiation of our Phase 2 study of CYB004, we are progressing quickly to potentially change the treatment paradigm for MDD and GAD and bring to market innovative treatment options for patients in need.”

“The path towards approval and commercialization for such novel therapeutics is gaining clarity. We believe our rigorous research and novel clinical approach can lead to a wholesale transformation in how mental health disorders are treated and ultimately, to improved outcomes for patients and their families. Cybin’s momentum continues, and 2024 will be another year of regulatory engagement and acceleration for our lead clinical programs. We are grateful for the financial support to continue this important work and look forward to sharing future updates on our progress,” concluded Drysdale.

Recent Business and Pipeline Highlights:

CYB003: Lead program with FDA BTD for the adjunctive treatment of MDD. This is the first known BTD granted by the FDA for an adjunctive psychedelic based therapy for the potential treatment of MDD. BTD provides an expedited review pathway and increased access to FDA guidance on trial design, with the potential to reduce drug development timelines. The designation includes all “fast track” program features, as well as more intensive FDA guidance and discussion of the CYB003 development program, including planned clinical trials and plans for expediting the manufacturing development strategy. BTD is supported by the Company’s positive topline results from its Phase 2 study of CYB003 in MDD, which demonstrated a robust, and clinically significant reduction in depressive symptoms after a single dose with a mean 14 point MADRS score reduction from baseline between CYB003 (12mg) vs. placebo (p=0.0005) at three weeks. At six weeks, 79% of patients were in remission from depression after receiving two doses of CYB003 (12mg).

Announced positive four-month durability data for CYB003 in MDD supporting progression to a pivotal Phase 3 multinational study of CYB003 in summer 2024. Robust and sustained improvements in symptoms of depression were observed with two doses of 12mg or 16mg of CYB003:

- Mean reduction from baseline in the MADRS total score was approximately 22 points from baseline in both dosing cohorts.
- Approximately 75% of the patients were responders (\geq 50% improvement in MADRS scores) following two doses of

16mg.

- 60% of patients on 12mg and 75% on 16mg were in remission from depression following 2 doses (MADRS score \leq 10).

CYB003 was well tolerated with no drug-related serious adverse events. All adverse events were mild or moderate in intensity. There were no incidents of suicidal ideation or behavior and no discontinuations due to adverse events.

Announced a positive End-of-Phase 2 meeting and alignment with the FDA on the CYB003 pivotal program design. The Company expects to initiate enrollment for the multinational, multisite Phase 3 program in summer of 2024. ¹ This is expected to be the first Phase 3 trial evaluating a deuterated psilocybin analog for the adjunctive treatment of MDD. Clinical site selection is complete for the first Phase 3 study, which will include thirty study sites across the United States and Europe, all of which are experienced with conducting psychedelic clinical trials.

CYB004: Initiated Phase 2 study of the Company's proprietary deuterated DMT molecule in development for the treatment of GAD. In January 2024, the FDA cleared the Company's Investigational New Drug application for CYB004. CYB004 is being developed as a potentially highly scalable intermittent treatment. A single intramuscular dose is expected to result in acute psychedelic effects lasting approximately 90 minutes. Results from this study 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.

Strengthened patent portfolio with the addition of 4 new patents in key jurisdictions.

- The United States Patent and Trademark Office ("USPTO") granted U.S. patent 11,958,807 in support of its CYB003 program. The patent includes claims to pharmaceutical compositions within the Company's CYB003 program and is expected to provide exclusivity until at least 2041.
- The Canadian Patent Office granted CA patent 3,179,335 and the Chinese Patent Office granted CN patent ZL202180044031.5 in support of the Company's CYB004 program. The patents include claims to pharmaceutical compositions within the CYB004 program and are expected to provide exclusivity until at least 2041.
- The Chinese Patent Office granted CN patent ZL202080087092.5 in support of the Company's CYB004 program. This patent includes claims to methods of synthesis of compounds within the CYB004 program and is expected to provide exclusivity until at least 2040.

Upcoming Clinical Milestones and Future Studies:¹

CYB003 - Deuterated Psilocybin Analog Program

- Initiate a multinational, multisite Phase 3 program in summer of 2024 to further evaluate the safety and efficacy of CYB003 capsules as a potential adjunctive treatment in a larger MDD patient population.

CYB004 – Deuterated DMT Program

- Topline safety and efficacy readout from Phase 2 GAD study expected around year end 2024.

Financial highlights

- Cash totaled C\$209 million as of March 31, 2024.
- With the completion of the Private Placement and a combination of the Company's current cash position, current at-the-market equity program ("ATM Program"), the Company has access to over C\$285 million. ²
- Net loss was C\$21 million for the quarter ended March 31, 2024, compared to a net loss of C\$14 million in the same period last year.
- Net loss was C\$78 million for the year ended March 31, 2024, compared to a net loss of C\$47 million in the same period last year.
- Cash-based operating expenses consisting of research, general, and administrative costs totaled C\$24 million for the quarter ended March 31, 2024, compared to C\$13 million, in the prior year quarter.
- Cash-based operating expenses consisting of research, general, and administrative costs totaled C\$65 million for the year ended March 31, 2024, compared to C\$47 million, in the prior year.
- Cash flows used in operating activities were C\$21 million for the quarter ended March 31, 2024, compared to C\$11 million in the same period last year.
- Cash flows used in operating activities were C\$69 million for the year ended March 31, 2024, compared to C\$47 million in the same period last year.
- Cash flows received from financing activities were C\$254.5 million for the year ended March 31, 2024, compared to C\$13.6 million in the same period last year, related to the net proceeds on the issuance of common shares through the Private Placement, a public offering completed on August 4, 2023, a public offering completed on November 14, 2023, a common share purchase agreement with Lincoln Park Capital Fund, LLC and the ATM 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 deuterated DMT 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.

Notes


1. There is no assurance that timelines will be met. Anticipated timelines regarding the initiation, advancement and results of clinical trials are based on reasonable assumptions informed by current knowledge and information available to the Company. See "Cautionary Notes and Forward-Looking Statements".
2. There can be no assurance that the Company will be successful in obtaining additional capital under the ATM Program.

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 summer 2024; the release of topline Phase 2 CYB004 data around year-end 2024; the Company's ability to access capital under the ATM Program; 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 year ended March 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 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. 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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