



Cybin Applauds FDA Commissioner Dr. Martin Makary's Call to Accelerate and Prioritize Research on Psychedelic Therapeutics

May 20, 2025

- U.S. Food and Drug Administration ("FDA") Commissioner identifies psychedelic drug development as a top agency priority in an effort to address unmet needs in mental health -

- Calls for FDA to be open to innovative treatments that show promise, even when they challenge traditional understanding of medicine -

- CYB003 granted Breakthrough Therapy Designation by the FDA for the adjunctive treatment of major depressive disorder ("MDD") -

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, applauds recent comments made by Dr. Martin Makary, Commissioner of the U.S. FDA relating to the importance of accelerating and prioritizing research on the clinical benefits of psychedelic therapeutics.

"It is gratifying that the FDA Commissioner shares our belief in the potential therapeutic value of these innovative treatments – a long-held belief that stands at the core of Cybin's mission," said Doug Drysdale, Chief Executive Officer of Cybin. "We are doing the rigorous investigative clinical work to unlock the potential of this class of drugs to effectively treat a variety of disorders, including major depressive disorder and generalized anxiety disorder. We agree wholeheartedly that the time is now to address the mental health crisis, and we applaud Dr. Makary's commitment to expedite the regulatory review process for product candidates in development and to get them into the hands of providers and patients as soon as possible."

"Cybin is committed to advancing its clinical-stage programs toward potential regulatory review and approval. Our CYB003 deuterated psilocin program, which is currently in Phase 3 development, has been granted FDA Breakthrough Therapy Designation for the adjunctive treatment of MDD which could expedite drug development timelines. We are encouraged by our ongoing positive interactions with the FDA and by the Agency's stated focus and openness to innovative treatments that show promise, even when they challenge traditional standards of care. This public endorsement that psychedelics are a "frontier area" with compelling scientific evidence is welcome validation for the work we do every day," concluded Drysdale.

Clinical Program Summary

CYB003: Deuterated Psilocin Program

Status: Dosing continues in Phase 3 APPROACH study in MDD. APPROACH is the first pivotal study in Cybin's Phase 3 PARADIGM program, which includes two 12-week randomized, placebo-controlled studies (APPROACH and EMBRACE) and a long-term extension study (EXTEND).

Summary of positive Phase 2 12-Month Efficacy Data in MDD Patients

- 100% of participants receiving two doses of 16 mg were responders.
- 71% of participants receiving two doses of 16 mg were in remission.
- Mean change from baseline in MADRS was approximately -23 points after two doses of 16 mg.

Upcoming Milestones: Initiate second pivotal Phase 3 study, EMBRACE, around mid-2025.

CYB004: Deuterated DMT Program

Status: Dosing is ongoing in Phase 2 study in generalized anxiety disorder (GAD)

Upcoming Milestones: Phase 2 GAD study is expected to complete mid-2025.

To watch Dr. Makary's interview, [click here](#).

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.

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 advancing clinical-stage programs toward potential regulatory review and approval; the potential for FDA Breakthrough Therapy Designation to accelerate drug development timelines; initiating a second pivotal Phase 3 study, EMBRACE, around mid-2025; completing a Phase 2 GAD study in mid-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 nine months ended December 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 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.

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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