



Cybin Highlights Neuropsychiatry Platform and Upcoming Clinical Milestones

September 23, 2025

- Successfully completed enrollment of 36 participants in Phase 2 study of CYB004, the Company's deuterated dimethyltryptamine ("DMT") program for the treatment of Generalized Anxiety Disorder ("GAD"). Topline data expected Q1 2026 -
- Continues to advance CYB003, the Company's proprietary deuterated psilocin analog, in Phase 3 studies for the adjunctive treatment of major depressive disorder ("MDD"). Dosing is ongoing in the first pivotal study, APPROACH, with expected enrollment of 220 patients across 45 U.S. clinical sites -
- Sector-leading intellectual property portfolio with 100+ granted patents and 250+ pending applications positions Cybin as a leader in Phase 3 psychedelic therapeutics -

TORONTO--(BUSINESS WIRE)--Sep. 23, 2025-- [Cybin Inc.](#) (NYSE American:CYBN) (Cboe CA:CYBN) ("Cybin" or the "Company"), a clinical-stage breakthrough neuropsychiatry company committed to revolutionizing mental healthcare through proprietary drug discovery platforms and innovative delivery systems, today highlights significant clinical and regulatory milestones and upcoming value-driving catalysts as the Company advances multiple programs towards potential commercialization.

"We have established a leading position in the psychedelic therapeutics space through Cybin's proprietary drug discovery platforms that combine novel deuterated molecules with innovative drug delivery systems. Our intellectual property portfolio represents one of the most comprehensive collections of patents in the neuropsychiatry sector, providing a potentially significant competitive moat across multiple indications and expected exclusivity until 2041," said Eric So, Interim Chief Executive Officer of Cybin.

Key Neuropsychiatry Platform Differentiators:

- **Novel Drug Delivery Systems:** Advanced formulation approaches, including oral and intramuscular delivery mechanisms, are optimized for clinical and commercial scalability.
- **Scalable Manufacturing Partnerships:** Thermo Fisher Scientific has been engaged to provide U.S.-based commercial-scale manufacturing capabilities for the CYB003 program.

Upcoming Milestones

CYB003 Phase 3 PARADIGM Program in MDD - Key Catalysts:

- APPROACH™ Study: Enrollment of 220 participants across 45 clinical sites in the U.S., with topline data expected in the fourth quarter of 2026
- EMBRACE™ Study: Initiation expected in Q4 2025, targeting 330 participants with moderate to severe MDD. EMBRACE has been granted approval to initiate in Australia, Ireland, Poland, Greece, and the United Kingdom
- EXTEND Long-Term Extension Study: Patient rollovers have begun, providing critical long-term safety and durability data
- FDA Breakthrough Therapy Designation provides expedited regulatory pathway and enhanced FDA guidance throughout development
- Phase 2 Durability: 100% response rates and 71% remission rates maintained at 12 months following two 16mg doses

CYB004 Phase 2 Program in GAD - Near-Term Value Catalyst:

- Successfully completed enrollment of 36 participants in September 2025
- Topline data expected first quarter of 2026
- Differentiated delivery: Intramuscular delivery mechanisms optimized for clinical and commercial scalability
- Market expansion opportunity: Data may position Cybin for dual indication development across MDD and GAD

Strategic Market Validation Through Recent M&A Activity

"The recent acquisition by AbbVie of Gilgamesh Pharmaceuticals' brexisiloin program supports our long-held thesis that IP and novel drug development platforms are fundamental value drivers in the neuropsychiatry space," continued So. "Cybin's extensive patent portfolio and proprietary deuteration technology provide us with significant competitive advantages as we advance toward potential regulatory approvals and commercial launch - all with the aim of addressing the substantial unmet need for improved mental health treatments. Broader recognition of the potential benefits of these therapeutics, together with this market momentum, are highly encouraging."

Commercial Infrastructure and Partnership Strategy

Manufacturing Excellence:

Cybin has established its manufacturing operations in the U.S. through its partnership with Thermo Fisher Scientific, encompassing both drug substance production and drug product capsule manufacturing. The Company's manufacturing strategy includes two dedicated facilities for Phase 3 clinical supply and future commercialization.

Commercial Preparation:

The Company has strategically partnered with Osmind, a leading service provider to psychiatry practices, to accelerate commercial preparation across its clinical-stage pipeline. This partnership provides access to over 800 psychiatry clinics in the U.S., point-of-care software, and real-world data capabilities.

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 promising class leading data, Cybin is working to change the mental health treatment landscape through the introduction of novel drugs that provide effective and durable results for patients. The Company is currently developing CYB003, a proprietary deuterated psilocin analog, in Phase 3 studies for the adjunctive treatment of major depressive disorder that has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration 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 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 or forward-looking information within the meaning of applicable securities laws (collectively, "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 expectation to release topline Phase 2 data for CYB004 in the first quarter of 2026; expectation to enroll 220 participants at 45 clinical sites across the United States for the APPROACH study; release of topline data from APPROACH study in the fourth quarter of 2026; initiation of EMBRACE study in the fourth quarter of 2025; expectation to enroll 330 participants in the EMBRACE study; 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 months ended June 30, 2025, and the Company's annual information form for the year ended March 31, 2025, 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/edgar. 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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