



Cybin Provides Corporate Update and Highlights Positive Regulatory Signals for Psychedelic Therapeutics

June 13, 2025

- Patient dosing is underway in the Phase 3 CYB003 PARADIGM program in Major Depressive Disorder ("MDD") with expected combined enrollment of approximately 550 participants across three studies (APPROACH™, EMBRACE™, and EXTEND) .

- Partnerships with Osmind and Thermo Fisher Scientific strengthen the Company's commercialization and manufacturing capabilities -

- Positive regulatory signals from U.S. Agencies amid expanding media coverage could expedite regulatory pathways across Cybin's clinical-stage pipeline -

TORONTO--(BUSINESS WIRE)-- [Cybin Inc.](#) (NYSE American:CYBN) (Cboe Canada 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 provided a corporate update.

"It is especially gratifying that at a time when we are advancing our clinical pipeline programs, with our lead program CYB003 in Phase 3 development, the path toward approval and eventual commercialization of psychedelic therapeutics is gaining clarity," said Doug Drysdale, Chief Executive Officer of Cybin. "With our expanded intellectual property portfolio, and a number of key partnerships in place, we believe our rigorous research and novel clinical approach can lead to a transformation in how mental health disorders are treated. Now is the time to address the mental health crisis, and we are encouraged by recent sentiment in favor of expediting the regulatory review process for product candidates in development."

Recent Corporate Highlights

- **Continued to expand its strategic clinical site partnership ("SPA") program in support of the Phase 3 PARADIGM program.** The SPA program is designed to facilitate collaboration among sites, enhance efficiency in trial operations, and improve overall site performance.
- **Partnered with Thermo Fisher Scientific, a world-class manufacturing partner, to provide U.S.-based manufacturing for the CYB003 program.** Cybin broadened its existing strong relationship with Thermo Fisher Scientific to include the development of both the drug substance and drug product capsules for CYB003.
- **Partnered with Osmind, a leading service provider to psychiatry practices in the U.S., with the objective of accelerating commercial preparation for clinical-stage pipeline.** Osmind advances psychiatry through technology and services to bring innovative mental health treatments to patients in need. Cybin will leverage Osmind's 800-clinic network, point-of-care software, and real-world data to support commercial preparation for its clinical-stage pipeline.
- **Continued to expand intellectual property portfolio with two additional U.S. patents supporting lead programs CYB003 and CYB004, bringing the total to over 90 granted patents and over 230 pending applications.** The recently issued patents are as follows:
 - U.S. patent 12,291,499 includes pharmaceutical compositions and oral dosage forms within the CYB003 program with expected exclusivity until 2041.
 - U.S. patent 12,318,477 is expected to provide exclusivity until 2040 and includes claims to novel formulations of DMT and deuterated isotopologues for intramuscular ("IM") injection, including CYB004.

Positive Regulatory Signals and Evolving Acceptance of Potential Therapeutic Value of Psychedelics

Recent statements and hiring decisions by senior U.S. Health and Human Services ("HHS") and FDA officials, in addition to ongoing signs of bipartisan congressional support, suggest an improved forward regulatory environment for psychedelic medicine and therapies, including the potential for accelerated approval pathways.

The Company believes that these developments, together with increased political recognition and public understanding of the science underpinning these programs, have the potential to expedite regulatory pathways and reduce overall risk across its clinical

portfolio. Highlights include:

- In a recent interview, FDA Commissioner Dr. Marty Makary stated that psychedelic-drug review is a “top priority” and promised an “expeditious and rapid review” of clinical data.¹
- Drug-policy lawyer, Matthew Zorn, has joined HHS as Deputy General Counsel to work on psychedelics policy. He previously challenged the government on matters such as allowing research on cannabis for veterans with PTSD, preventing tryptamines from being scheduled, and fighting for patient access to psilocybin under Right to Try laws.²
- Navy-SEAL-turned-Congressman Morgan Luttrell recently urged the GOP to “embrace” compounds such as psilocybin, MDMA and ibogaine to help veterans with PTSD.³
- President Trump’s new pick for surgeon general, Dr. Casey Means, wrote in a recent book that people should consider guided-psychedelic therapy.⁴
- Cybin’s Chief Executive Officer Doug Drysdale recently appeared on Fox News and is increasingly sought by media outlets as a trusted commentator.⁵

On June 19, 2025, Doug Drysdale will speak in a panel discussion focused on the regulatory landscape and next steps for potential commercialization, at the Psychedelic Science 2025 Conference taking place June 16-20, 2025, in Denver, Colorado. The panel details are as follows:

Panel Title: The Home Stretch: Pivotal Trials and Preparing for Launch

Date and Time: Thursday, June 19, 2025, at 9:30 a.m. MDT (11:30 a.m. EDT)

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 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.

Sources

1. NewsNation, “FDA Commissioner Says Research on Psychedelic Treatment ‘Top Priority,’” interview with FDA Commissioner Dr. Marty Makary, video posted May 16, 2025, <https://www.youtube.com/watch?v=KEQFKBME668> (accessed June 9, 2025).
2. Politico, “A Psychedelics Hire at HHS,” newsletter article, published May 28 2025, <https://www.politico.com/newsletters/future-pulse/2025/05/28/a-psychedelics-hire-at-hhs-00371416> (accessed June 9 2025).
3. The Wall Street Journal, “Lawmaker ‘Reborn’ Through Psychedelic Therapy Wants the GOP to Embrace It,” news article, published May 17 2025, <https://www.wsj.com/politics/policy/republican-psychedelic-drug-therapy-fc313ea2> (accessed June 9 2025).
4. The Associated Press, “Trump Surgeon General Pick Praised Unproven Psychedelic Therapy, Said Mushrooms Helped Her Find Love,” news article, published May 14 2025, <https://apnews.com/article/means-trump-surgeon-general-mushrooms-psychedelic-drugs-72c22ed077409b4bb865214e7ef304a8> (accessed June 9 2025).
5. Fox News. “Trump Administration Exploring Potential Benefits of Psychedelic Treatments.” America’s Newsroom, correspondent Alexandria Hoff, broadcast June 5 2025. Video clip, 1:58. <https://www.foxnews.com/video/6373914669112>

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 plans to enroll participants and add additional clinical sites for the PARADIGM program; regulatory statements that suggest an expedited regulatory pathway for Cybin programs; the anticipated approval and commercialization of CYB003 and CYB004; the ability to accelerate commercial preparation of clinical-stage programs through the Company’s partnership with Osmind; 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, 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/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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