

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of January, 2025.

Commission File Number: **001-40673**

Cybin Inc.

(Exact Name of Registrant as Specified in Charter)

100 King Street West, Suite 5600, Toronto, Ontario, M5X 1C9
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☐ Form 40-F ☒

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CYBIN INC.

(Registrant)

Date: January 13, 2025

By: /s/ Doug Drysdale

Name: Doug Drysdale

Title: Chief Executive Officer

EXHIBIT INDEX

99.1 [News Release dated January 13, 2025](#)



Cybin Highlights 2024 Accomplishments and Upcoming Milestones for 2025

- *Announced positive Phase 2 Data for CYB003, Demonstrating Breakthrough 12-Month Efficacy in Treating Major Depressive Disorder ("MDD") -*
- *Initiated PARADIGM: A Multinational Pivotal Phase 3 Program Evaluating CYB003 for the Adjunctive Treatment of MDD –*
- *Received U.S. Food and Drug Administration ("FDA") Breakthrough Therapy Designation ("BTD") for CYB003 for the Adjunctive Treatment of MDD -*
- *Topline efficacy data from Phase 2 Proof-of-Concept Study of CYB004 in Generalized Anxiety Disorder ("GAD") expected in Q1 2025 -*
- *Expanded clinical expertise in key roles to support clinical advancement and pipeline development -*

TORONTO, CANADA – January 13, 2025 – [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, is pleased to provide a year-end summary of its key accomplishments in 2024 and upcoming milestones for 2025.

"In 2024, we made significant progress toward our goal of transforming the mental health treatment landscape," said Doug Drysdale, Chief Executive Officer of Cybin. "Our clinical pipeline of tryptamine serotonin receptor agonists – notably CYB003, our proprietary deuterated psilocin program in development for the adjunctive treatment of MDD, and CYB004, our deuterated dimethyltryptamine, in intramuscular ("IM") form being developed for the treatment of GAD - achieved several critical benchmarks."

“It’s noteworthy that in March 2024, CYB003 received FDA Breakthrough Therapy Designation. Among its many benefits, this designation provides an expedited review pathway and the potential to accelerate drug development timelines. It also includes all “fast track” program features and acknowledges the significant unmet medical need for more effective treatments of MDD. This is especially gratifying in light of our Phase 2 study results of CYB003 in MDD, which showed remarkable efficacy at 12 months, including a 100% response rate and a 71% remission rate among participants who received two 16 mg doses. With these outstanding findings in hand, we initiated PARADIGM™, our multinational pivotal Phase 3 program, evaluating CYB003 in MDD patients. We also commenced our Phase 2 proof-of-concept study of CYB004 in GAD. I’m proud of our Research and Development team and the tremendous progress made in a relatively short amount of time.”

“Looking ahead, we are excited about Cybin’s next phase of investigation and growth and for the upcoming milestones, including a readout of topline efficacy data from our CYB004 Phase 2 GAD study in the first quarter of 2025 and the initiation of the EXTEND and EMBRACE components of our Phase 3 PARADIGM program,” concluded Drysdale.

2024 Highlights:

CYB003

- **Announced unprecedented 12-month efficacy data from the completed Phase 2 study of CYB003**
 - 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 ~23 points after two doses of 16 mg
- **Initiated PARADIGM, a multinational pivotal Phase 3 program evaluating CYB003 for the adjunctive treatment of MDD**
 - PARADIGM comprises two 12-week randomized, placebo-controlled studies (APPROACH™ and EMBRACE™) and a long-term extension study (EXTEND)
 - APPROACH has been initiated and will enroll 220 participants at 36 clinical sites across the U.S. and Europe; topline results expected in 2026
 - EMBRACE will enroll 330 participants at sites across the U.S. and Europe and is expected to commence by mid 2025
 - EXTEND is expected to begin 12 weeks after commencement of APPROACH and EMBRACE, respectively
- **Appointed senior clinical team leaders and expanded its clinical operations team in support of its PARADIGM program.** The new team members provide significant expertise and decades of experience across critical domains that are integral to the pivotal Phase 3 program.

- **Received additional U.S. patent in support of its CYB003 Breakthrough Therapy Program.** The patent is expected to provide exclusivity until at least 2041 and includes claims to pharmaceutical compositions within the Company's proprietary deuterated psilocin analog program. This brings the total number of granted patents to over 70, with more than 220 patents currently pending.

CYB004

- **Initiated Phase 2 proof-of-concept study of CYB004 in GAD.**
 - The Phase 2 study is a randomized, double-blind study evaluating the safety and efficacy of CYB004 in participants with GAD, with concomitant antidepressant/anxiolytic treatment and co-morbid depression allowed
 - The Phase 2 study is being conducted at sites in the U.S., with topline safety and efficacy results expected in Q1 2025

Presented two posters at the American College of Neuropsychopharmacology (“ACNP”) Meeting. The data presented include 12-month efficacy results from the Company's Phase 2 study of CYB003, its deuterated psilocin program, in MDD, which showed durable response and remission rates at 12 months, in addition to results from a completed Phase 1b study exploring drug-drug interactions between N,N-dimethyltryptamine (“DMT”) and selective serotonin reuptake inhibitors (“SSRIs”), in MDD patients.

CYB005

- Announced grant of first U.S. Composition of Matter patent in support of its CYB005 phenethylamines program. Cybin is investigating novel molecules within the CYB005 program at non-hallucinogenic doses for a range of Central Nervous System disorders and continues to explore non-hallucinogenic neuroplastogens within its broader discovery pipeline.

First-Half 2025 Expected Milestones

- Topline efficacy data readout from CYB004 Phase 2 GAD study in Q1 2025
- Initiate EXTEND and EMBRACE pivotal studies of CYB003

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 the Company’s plans to report Phase 2 topline results for CYB004 in Q1 2025; timing of the initiation and ability of the Company to enroll participants for the PARADIGM program; the potential for BTD to accelerate drug development timelines; 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 six month ended September 30, 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.

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