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 August, 2024.

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: August 13, 2024

By: */s/ Doug Drysdale*
Name: Doug Drysdale
Title: Chief Executive Officer

EXHIBIT INDEX

99.1	News Release dated August 13, 2024

Cybin Announces Completion of FDA Type B Initial Breakthrough Therapy Meeting and Plans for CYB003 Phase 3 Program in Major Depressive Disorder

- Company expects to initiate Phase 3 pivotal trial in late summer 2024 -

- Phase 3 pivotal study to include 30 clinical sites across the United States and Europe with deep expertise in depression studies -

- Pivotal trial designs incorporate elements to address functional unblinding -

- Company to report 12-month Phase 2 efficacy data for CYB003 in Major Depressive Disorder ("MDD") in Q4 2024 -

TORONTO, CANADA – August 13, 2024 – 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, today announced that it held a Type B Initial Breakthrough Therapy Meeting with the U.S. Food and Drug Administration ("FDA") late last week in Washington, D.C. The Company plans to initiate its Phase 3 pivotal trial of CYB003 for the adjunctive treatment of MDD in late summer of 2024

"Following our productive Type B meeting, we continue to expect to commence our Phase 3 pivotal program in late summer," said Doug Drysdale, Chief Executive Officer of Cybin. "Having selected 30 clinical sites across the United States and Europe, we are eager to initiate this next phase of clinical development and to build on the positive impact of CYB003 to date. In our Phase 2 study, CYB003 showed a robust and sustained effect, with 75% of patients in remission from depression four months after two 16mg doses. We expect to report 12-month efficacy data from the Phase 2 study in the fourth quarter of this year. We look forward to ongoing engagement with the FDA as we advance our path to bringing new, improved treatment options to patients and providers."

Further to recent industry discussions around the subject of functional unblinding, the Company plans to implement multiple measures to attempt to mitigate the risk of functional unblinding in its pivotal study program, as follows:

- The pivotal study program will include one study with a three-arm design with a high dose, mid-dose, and placebo arm. Patients will not know if they received the therapeutic high dose or the sub therapeutic mid-dose, mitigating the unblinding to an extent and addressing potential expectancy bias;
- The study will utilize remote, independent, blinded raters who will not have any information on the dose received or the participant's dosing experience;
- The reporting of effects during the dosing session will be firewalled to ensure that the study team stays blinded;
- The studies will recruit participants who are largely psychedelic naïve to reduce the impact of expectancy bias;
- The studies will assess long-term efficacy data points up to one year, to outlast any potential expectancy effects.

In addition, the study will include manual and real time artificial intelligence screening of monitoring sessions to ensure monitor fidelity and patient safety.

The Company also today announced the realignment of the composition of its Governance and Nominating Committee, and Compensation Committee which will now be comprised solely of existing independent Directors Eric Hoskins (Chair), Mark Lawson, and Theresa Firestone; and Grant Froese (Chair), Mark Lawson and Theresa Firestone, respectively.

About Cybin

Cybin is a clinical-stage breakthrough neuropsychiatry company on a mission to create safe and effective next-generation 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 program for the treatment of major depressive disorder and CYB004, a proprietary dDMT 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.

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 late summer 2024; the release of 12-month durability data from Phase 2 study of CYB003 in Q4 2024; commencing enrollment at 30 clinical sites across the U.S. and Europe; 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, 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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