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 March, 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: March 14, 2024

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

EXHIBIT INDEX

99.1	News Release dated March 14, 2024

Cybin Announces Positive End-of-Phase 2 Meeting with FDA for CYB003 in Major Depressive Disorder and Phase 3 Program Design

- With U.S. Food and Drug Administration ("FDA") alignment on multisite, multinational Phase 3 program design Company expects to commence Phase 3 program around mid-year 2024 -

- 15 U.S. clinical trials sites targeted; European sites to be added -

- Robust and sustained improvement in depression symptoms with CYB003 at four months with 75% of patients in remission from depression after two doses (16mg) -

- Breakthrough Therapy Designation ("BTD") for CYB003 provides an expedited review pathway and increased engagement with the FDA -

This news release constitutes a "designated news release" for the purposes of Cybin's prospectus supplements each dated August 23, 2023, to its short form base shelf prospectus dated August 17, 2023, as amended December 22, 2023.

TORONTO, CANADA – March 14, 2024 – Cybin Inc. (NYSE American:CYBN) (Cboe CA:CYBN) ("**Cybin**" or the "**Company**"), a clinical-stage biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative next-generation psychedelic-based treatment options, today announced a positive End-of-Phase 2 meeting with the FDA for CYB003, its deuterated psilocybin analog for the adjunctive treatment of Major Depressive Disorder ("MDD").

This program will be the first ever adjunctive Phase 3 deuterated psilocybin analog depression study globally and follows the successful completion of the Company's Phase 2 study in MDD completed at the end of 2023. The Company has received minutes from its End-of-Phase-2 meeting with the FDA and reached alignment on its Phase 3 program design. The Company intends to commence enrollment for the multinational, multisite Phase 3 program in mid-year 2024. Fifteen U.S. study sites have been targeted, all of which have experience running psychedelic clinical trials and are DEA Schedule I licensed. The preliminary targeting of specific study sites will serve to expedite site initiation. The Company intends to add approximately 8 additional sites in Europe.

The Company has engaged Worldwide Clinical Trials ("Worldwide"), a global, full-service contract research organization with deep expertise managing clinical trials for mental health conditions, including major depressive disorder. Worldwide has a track record of successful patient recruitment for psychedelic trials and global relationships with best-in-class investigative sites. Worldwide has recent experience managing psychedelic studies in psychiatric populations, including clinical trials conducted in the U.S., Canada, United Kingdom, and other European countries, across a range of psychedelic compounds and treatment models.

"We are very pleased with the results of our End-of-Phase 2 meeting with the FDA and appreciate the agency's thoroughness and guidance during the process. Having aligned on key features of the pivotal program, we look forward to initiating a multisite, multinational Phase 3 program around mid-year," said Doug Drysdale, Chief Executive Officer of Cybin. "The strength of CYB003's clinical profile to date, which showed that at four-months after dosing, across the two doses, 60% of patients receiving 12 mg and 75% of patients receiving 16 mg of CYB003 achieved remission from depression symptoms. With positive durability data demonstrating sustained effects up to at least four months, BTD, and alignment with the FDA on our Phase 3 plan, we are positioned to move quickly to progress the program and bring relief and treatment alternatives to people who are desperately waiting," concluded Drysdale.

CYB003 Phase 3 Pivotal Program Outline

The Phase 3 pivotal program will comprise two adequate and well controlled studies and a long-term extension, designed as follows:

- CYB003-002 (n=220): Fixed repeat dose study of 16mg CYB003, with two doses 3- weeks apart compared to two doses of placebo. The trial is designed to replicate the treatment response seen in the Company's Phase 2 study.
- CYB003-003 (n=330): Three-arm fixed repeat dose study of CYB003 (16mg or 8mg), with two doses 3-weeks apart. Each active arm will be compared to two doses of placebo.
- The primary endpoint of both studies is the change in MADRS total score from baseline at Week 6, with a secondary endpoint at Week 12, each compared to placebo.
- Patients from each of these Phase 3 trials will enroll in a one-year extension study, during which time non-responders and relapsing patients will receive one full cycle of CYB003 16mg (two doses, three weeks apart).
- Moderate to severe MDD patients enrolled in both studies (MADRS >/=24) will be on stable doses of background antidepressant medication, positioning CYB003 as a convenient, adjunctive treatment option.
- CYB003-002 is anticipated to begin around mid-year 2024, with CYB003-003 anticipated to initiate a few months later. Each study is expected to run for approximately 18-24 months.

Patient recruitment for the Phase 3 program will include a broad MDD population including only patients that are currently on antidepressants. Importantly, patients will not be required to titrate off their background antidepressants which will reduce some of the inherent recruitment challenges seen in other depression studies.

Summary of Positive Four-Month Efficacy Data for CYB003

- Robust and sustained improvements in symptoms of depression four months after two doses of 12mg or 16mg of CYB003:
  - Mean reduction from baseline in the MADRS total score was approximately 22 points from baseline in both dosing cohorts.
    - Approximately 75% of the patients were responders (>/= 50% improvement in MADRS scores) following two doses of 16mg.
    - 60% of patients on 12mg and 75% on 16mg were in remission from depression following 2 doses (MADRS score </= 10).

Safety and tolerability:

- CYB003 was well tolerated with no drug-related serious adverse events.
- All adverse events were mild or moderate in intensity.
- No incidents of suicidal ideation or behavior.
- No discontinuations due to adverse events.

Earlier this week, Cybin announced the granting of BTD for CYB003 by the FDA. If approved by the FDA, CYB003 would be the first known adjunctive psychedelic-based therapeutic for the treatment of MDD.

BTD provides an expedited review pathway, as well as increased access to FDA guidance on trial design, with the potential to reduce drug development timelines. It is reserved for drug candidates that target serious conditions and demonstrate substantial improvement on a clinically significant endpoint over available therapies. The designation includes all “fast track” program features, as well as more intensive FDA guidance and discussion of the CYB003 development program, including planned clinical trials and plans for expediting the manufacturing development strategy. CYB003 is eligible for Priority Review and Accelerated Approval.

The designation of CYB003 as a breakthrough therapy acknowledges the significant unmet medical need for more effective treatments of MDD and supports CYB003’s potential for significant improvements over existing therapies.

About Cybin

Cybin is a clinical-stage biopharmaceutical company on a mission to create safe and effective psychedelic-based 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, and novel formulation approaches and treatment regimens. The Company is currently developing CYB003, a proprietary deuterated psilocybin analog for the treatment of major depressive disorder and CYB004, a proprietary deuterated DMT 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 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”, “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 planned clinical trials and program strategy for CYB003; plans for additional European study sites; the potential for CYB003 to provide significant improvement over existing therapies; the advancement of CYB003 towards a Phase 3 trial in mid-2024; the potential reduction in drug development timelines afforded by BTD; and the Company’s proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health disorders.

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: implications of the spread of COVID-19 on the Company's operations; 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; 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, 2023, and the Company’s annual information form for the year ended March 31, 2023, 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. Cybin has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that Cybin verified such in clinical trials or that Cybin will complete such trials. 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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