

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 May, 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: May 6, 2024

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

EXHIBIT INDEX

99.1 [News Release dated May 6, 2024](#)



Cybin Provides Corporate Update and Highlights Upcoming Clinical Milestones

- *Recent U.S. \$150 Million funding round lead by a syndicate of leading biopharmaceutical institutional investors supports advancement of clinical-stage programs CYB003 and CYB004 -*
- *Received U.S. Food and Drug Administration ("FDA") Breakthrough Therapy Designation ("BTD") for CYB003, a proprietary deuterated psilocybin analog in development for the adjunctive treatment of Major Depressive Disorder ("MDD") -*
- *Initiation of pivotal CYB003 Phase 3 study in MDD expected in mid-2024 -*
- *Phase 2 topline efficacy and safety results for CYB004 in Generalized Anxiety Disorder ("GAD") expected Q4 2024 -*

TORONTO, CANADA – May 6, 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, provides a corporate update highlighting recent clinical accomplishments and key upcoming catalysts across its development pipeline.

"With the prevalence and burden of mental health conditions at an all-time high, there is an urgent and growing need for improved treatments for depression and anxiety. Our team is dedicated to turning the tide of the mental health crisis through our clinical-stage programs," said Doug Drysdale, Chief Executive Officer of Cybin. "The past several months have been pivotal with FDA Breakthrough Therapy Designation for CYB003 and alignment on the Phase 3 design in major depressive disorder, and the start of our Phase 2 study of CYB004 in Generalized Anxiety Disorder. We are progressing quickly with both programs and expect the coming months to be transformative for Cybin, with a Phase 3 trial of CYB003 in MDD expected to begin this summer, and Phase 2 topline efficacy data for CYB004 in Q4 2024. The recent funding round provides us with the runway to achieve these important milestones."

CYB003: Lead program with FDA Breakthrough Therapy Designation for the adjunctive treatment of MDD

CYB003 is the first ever deuterated psilocybin analog program to enter clinical development and has demonstrated rapid and robust improvements in symptoms of depression with a single dose in a Phase 2 MDD study, with an incremental clinical benefit from a second dose and durable effects which were sustained to four months. The BTB by the FDA validates CYB003's potential to show significant clinical improvements over existing treatments based on preliminary results and serves to expedite CYB003's development pathway towards commercialization. Having achieved BTB and FDA alignment on a Phase 3 program design for CYB003, the Company plans to initiate a multinational, multisite Phase 3 MDD study in the summer of 2024.

Positive Phase 2 Results for CYB003 in MDD

- Rapid and large improvements in symptoms of depression after single doses with average 13.75 point difference in MADRS score reduction between CYB003 (12mg and 16mg pooled) and placebo at 3 weeks ($p < 0.0001$)
- Incremental benefit of second dose with $>75\%$ response rates and up to 80% remission rates (12 mg) after second dose
- Efficacy sustained at 4 months after 2 doses, with a mean 22-point reduction in MADRS scores from baseline and robust remission rates of 60% (12 mg) and 75% (16 mg)
- Excellent safety and tolerability profile, with all reported AEs mild to moderate

CYB004: A proprietary deuterated N,N-dimethyltryptamine ("DMT") program in development for the treatment of GAD

CYB004 is being developed as a highly scalable intermittent treatment. A single intramuscular ("IM") dose is expected to result in acute psychedelic effects lasting an average of 90 minutes. The Company has initiated a Phase 2 study of IM CYB004 in participants with moderate to severe GAD, with topline data expected in Q4 2024. Results from this study are expected to provide proof-of-concept for CYB004's efficacy in GAD, time to onset of effects, and durability of effects to one year.

CYB004 Phase 2 Program Outline

- Randomized, double-blind study in 36 participants with moderate to severe GAD (GAD-7 score ≥ 10) with concomitant antidepressant/anxiolytic treatment and co-morbid depression allowed.
- Two IM doses, three weeks apart vs. two low-dose controls
- Primary endpoint is change in Hamilton Anxiety Rating Scale ("HAM-A") score from baseline at 6 weeks following second dose
- Other endpoints include the Montgomery-Asberg Depression Rating scale depression assessment, safety assessments, MEQ30 (psychedelic experience assessment) and EQ-5D-5L (quality of life assessment).

- Participants will be followed for a period of three months, with additional follow-up assessments up to a year
- Topline safety and efficacy results in Q4 2024

Intellectual Property

The Company's intellectual property portfolio comprises over 50 granted patents and over 170 pending applications. The issued patents and pending applications cover a broad range of molecules, drug combinations and delivery mechanisms including but not limited to amorphous psilocybin, psilocybin analogs, tryptamine derivatives, tryptamines compositions, inhalation delivery methods, combination drug therapies, and multiple classes of phenethylamine molecules. The Company's intellectual property includes composition of matter patents supporting its clinical-stage CYB003 and CYB004 programs.

Clinical Facilitator Training Program ("EMBARK")

EMBARK is a transdiagnostic, trans-drug, flexible model of psychological support for studies with psychedelics and provides facilitators the foundational training needed to provide skillful and ethical care to work with psychedelic therapeutics. The EMBARK Open Access platform is a free online course that offers foundational psychedelic facilitation training for healthcare professionals before they undergo a full training program. Cybin is also developing EMBARK for Clinical Trials ("EMBARK^{CT}"), a scalable model of psychedelic facilitation training that will enable the Company to effectively screen, qualify, and train facilitators to participate in future pivotal trials.

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 plan to initiate a multinational, multisite Phase 3 program around mid-year 2024; the potential reduction in drug development timeline afforded by BTD; the Company’s planned clinical trials and program strategy for CYB004; the anticipated release of Phase 2 topline data for CYB004 in Q4 2024; 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.

Investor & Media Contact:

Gabriel Fahel
Chief Legal Officer
Cybin Inc.
1-866-292-4601

irteam@cybin.com – or – media@cybin.com