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 15, 2024

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

EXHIBIT INDEX

99.1	News Release dated March 15, 2024

Cybin Initiates Phase 2 Proof-of-Concept Study of CYB004 in Generalized Anxiety Disorder

- Anxiety disorders are the most prevalent mental health disorders globally[1], contributing to over 28 million disability-adjusted life years ("DALYs")[2] -

- Highly scalable intermittent treatment for Generalized Anxiety Disorder ("GAD") with an expected treatment time of approximately 90-minutes from a single administration -

- Proprietary deuterated dimethyltryptamine ("DMT") molecule with U.S. composition of matter patent granted with protection expected through 2041 -

- Topline Phase 2 safety and efficacy data expected Q4 2024 -

TORONTO, CANADA – March 15, 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 the initiation of a Phase 2 proof-of-concept study of CYB004, its proprietary DMT molecule in development for the treatment of GAD. In January 2024, the U.S. Food and Drug Administration ("FDA") cleared Cybin's Investigational New Drug application for CYB004.

"Initiation of the Phase 2 study of CYB004 for GAD is an exciting step forward for our deuterated DMT program," said Doug Drysdale, Chief Executive Officer of Cybin. "One of our most important goals is to achieve a scalable, short-duration psychedelic experience for the patient, in the hopes of potentially disrupting negative, ruminative thought patterns. We are building on foundational investigative work from our Phase 2a trial of intravenous SPL026 (DMT) which showed preliminary evidence of effectiveness treating anxiety with rapid onset of antidepressant effects and reduction in anxiety scores."

“This week, we also announced three important catalysts for our other novel psychedelic molecule, CYB003 for the adjunctive treatment of Major Depressive Disorder: (1) we had a positive End-of-Phase 2 meeting with the FDA, gaining alignment on our Phase 3 program design; (2) CYB003 was granted Breakthrough Therapy Designation by the FDA; and (3) we shared positive four-month durability data which support a pivotal Phase 3 multinational study in mid-2024. With two lead clinical programs progressing rapidly, we are committed to leading the way to address the challenges of mental healthcare today,” concluded Drysdale.

CYB004 Phase 2 Program Outline

The CYB004-002 Phase 2 study is a randomized, double-blind study which will evaluate the safety and efficacy of CYB004 in participants with GAD, with concomitant antidepressant/anxiolytic treatment and co-morbid depression allowed.

- The study will recruit approximately 36 participants, who will be randomized in a double-blind manner, into 2 groups: the first group will receive two IM doses of CYB004, three weeks apart, while the second group will receive two low-dose control administrations.
- The study will enroll participants with moderate to severe GAD and a score of ≥10 on the GAD-7 anxiety scale.
- Participants will be followed for a period of three months, with an optional additional assessment at six months.
- The primary endpoint is a change in the Hamilton Anxiety Rating Scale (“HAM-A”) score from baseline at six weeks following the 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).
- Results from this study are expected to provide proof of concept for CYB004’s efficacy in GAD, the time to onset of effects, as well as durability of effects to six months.
- Topline safety and efficacy data from this Phase 2 CYB004-002 study are expected in Q4 2024.

Significant Unmet Medical Need in Generalized Anxiety Disorder

Anxiety disorders affect over 40 million adults in the United States each year.[3] In the U.S., GAD is the most common anxiety disorder seen in primary care, with a 12-month prevalence of 2.9%.[4] Despite the use of existing therapies, 50% of patients with GAD do not respond to first line treatment with antidepressants such as SSRIs and SNRIs[4], highlighting a large treatment gap and urgent need for improved therapeutic options.

Sources

1. Stein, D. J., Scott, K. M., de Jonge, P., & Kessler, R. C. (2017). Epidemiology of anxiety disorders: from surveys to nosology and back. *Dialogues in clinical neuroscience*, 19(2), 127–136. https://doi.org/10.31887/DCNS.2017.19.2/dstein
2. Yang X., Fang Y., Chen H., Zhang T., Yin X., Man J., Yang L., Lu M. (2021). Global, regional and national burden of anxiety disorders from 1990 to 2019: results from the Global Burden of Disease Study 2019. *Epidemiology and Psychiatric Sciences* 30, e36, 1–11.
3. https://adaa.org/understanding-anxiety/facts-statistics
4. Ansara E. D. (2020). Management of treatment-resistant generalized anxiety disorder. The mental health clinician, 10(6), 326–334. https://doi.org/10.9740/mhc.2020.11.326

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 CYB004; anticipated release of topline safety and efficacy from the Phase 2 CYB004-002 study in Q4 2024; the potential of CYB004 to be a scalable treatment that can be delivered in a short period of time; 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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