

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, 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: January 4, 2024

By: /s/ Doug Drysdale

Name: Doug Drysdale

Title: Chief Executive Officer

EXHIBIT INDEX

99.1 [News Release dated January 4, 2024](#)



Cybin Highlights Recent Topline Results and Outlines Key Upcoming Milestones Across its Clinical Development Programs

- *Recently announced positive Phase 2 topline data in Major Depressive Disorder ("MDD") with 79% of patients in remission from depression after two doses of CYB003 (12mg) -*
- *Programs supported by robust intellectual property portfolio with 40 granted patents and over 170 pending applications -*
- *Multinational operations support scaling to Phase 3 trial of CYB003 in MDD and Phase 2 study of deuterated dimethyltryptamine ("dDMT") in Generalized Anxiety Disorder ("GAD") in early 2024 -*
- *Phase 1 deuterated DMT readouts (CYB004/SPL028) in final analysis -*

TORONTO, CANADA – January 4, 2024 – [Cybin Inc.](https://www.cybin.com) (NYSE American:CYBN) (NEO: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 outlined its recent positive Phase 2 CYB003 topline results in MDD and near-term milestones across its clinical-stage deuterated psilocybin and dDMT programs in development for the treatment of multiple mental health conditions.

"The recently reported safety and efficacy datasets from our lead clinical programs compare extremely favorably to currently approved treatments for depression and anxiety disorders, where there remain significant unmet needs for patients. The first quarter of 2024 should be another active and productive period for us, as we advance our clinical programs. For CYB003, we expect to have 12-week efficacy data and an end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"). That discussion will inform the design of a Phase 3 study, which we plan to commence around the end of the first quarter. For our dDMT programs, we plan to initiate a Phase 2 trial of CYB004 in generalized anxiety disorder ("GAD")," said Doug Drysdale, Chief Executive Officer of Cybin. "As we look ahead, we see enormous opportunities for progress across our differentiated programs and development pipeline. With each promising dataset, we gain confidence in our ability to revolutionize the treatment of mental health disorders and to give patients and providers hope for longer lasting and improved outcomes."

CYB003: Deuterated Psilocybin Analog Program for the Treatment of MDD

The Company completed a Phase 1/2a study evaluating CYB003, a proprietary deuterated psilocybin analog, as an adjunctive therapy in participants with moderate to severe MDD. The Phase 2 results, which showed robust improvements in depression symptoms after single doses of CYB003, and a 79% remission rate from depression symptoms at six weeks after two doses of CYB003 (12mg), support progression to a multinational, multisite Phase 3 trial in early 2024.

The CYB003 program is supported by two composition of matter patents expected to provide coverage until at least 2041.

Summary of CYB003 Phase 2 topline efficacy data:

- 79% of patients remained in remission from their depression 6 weeks after receiving two doses of CYB003 (12mg)¹
- Rapid and large improvements in symptoms of depression observed after single doses of CYB003:
 - A mean -13.75 point difference in Montgomery–Asberg Depression Rating Scale score (“MADRS”) between CYB003 (12mg and 16mg cohorts pooled) and placebo which is statistically significant at 3 weeks ($p < 0.0001$).²
- Clear incremental benefit of a second dose:
 - Incremental and sustained benefit seen as a further 5.8 point improvement on the MADRS total score with a second dose of CYB003 (12mg) at 6 weeks.
- Magnitude of improvement far superior compared to approved antidepressants and recently reported data with other psychedelics:
 - Effects translate into unprecedented effect size (Cohen's $d > 2$) (SSRIs = 0.243)
 - These results compare favorably to pooled data from 232 industry studies of current standard of care antidepressants, selective serotonin reuptake inhibitors (“SSRIs”), submitted to U.S. Food and Drug Administration (“FDA”) which show an average improvement of 1.82 points on the MADRS total score vs. placebo³
- Demonstrated an excellent safety profile in doses tested, with all reported adverse events mild to moderate and self-limiting.

Upcoming Milestones for CYB003 Program

- Additional Phase 2 data assessing durability of efficacy for CYB003 at 12 weeks expected in Q1 2024.
- FDA end of Phase 2 meeting in early 2024.
- Initiate Phase 3 trial of CYB003 in MDD in early 2024, with recruiting expected to begin around the end of Q1 2024.

DMT Program (CYB004, SPL028, SPL026)

Cybin's portfolio includes the most advanced and extensive DMT dataset in the psychedelic drug development sector. The Company's DMT portfolio is comprised of dDMT molecules CYB004 and SPL028, which have the potential for less invasive, more convenient and patient-friendly dosing methods, in addition to SPL026, intravenous ("IV") DMT. CYB004, Cybin's proprietary dDMT molecule, is protected by a U.S. composition of matter patent expected to provide coverage until at least 2041.

Program Highlights:

The Company has completed multiple clinical trials providing proof-of-concept for its DMT/dDMT assets, including:

- Phase 2a safety and efficacy for SPL026 (IV DMT) in 34 participants with MDD, demonstrating a clinically relevant and statistically significant reduction in depression symptoms at two weeks after dosing (-7.4 point difference in MADRS between SPL026 and placebo). A durable antidepressant response and remission rates were observed at 6 months. Among participants who had achieved remission within three months with SPL026, 64% sustained remission to 6 months.
- Phase 1 studies evaluating intramuscular ("IM") SPL026 and SPL028 supporting IM administration for patient-friendly dosing, with Phase 1 IM/IV SPL028 data expected early Q1 2024.
- Phase 1b study evaluating the safety and efficacy of SPL026 in conjunction with SSRIs in 17 participants with MDD, demonstrating a favorable safety profile and enhanced efficacy when SPL026 was administered with SSRIs, and a 92% remission rate at 4 weeks in the SSRI cohort (n=12).
- Phase 1 study evaluating safety, dosing, and pharmacokinetics ("PK") and pharmacodynamics ("PD") of IV DMT and CYB004, with upcoming data expected to inform next steps for Phase 2.

Upcoming Milestones for dDMT Program:

- Phase 1 topline data for CYB004 expected early Q1 2024.
- Phase 1 data for IM/IV SPL028 expected early Q1 2024.
- Initiate Phase 2 GAD study in Q1 2024.

Footnotes

- 1) n=32 total: n=22 on CYB003; n=10 on placebo
- 2) n=34 total: n=24 on CYB003; n=10 on placebo
- 3) Stone et al. (2022) Response to acute monotherapy for major depressive disorder in randomized, placebo controlled trials submitted to the US Food and Drug Administration: individual participant data analysis. BMJ 2022;378:e067606 <https://doi.org/10.1136/bmj-2021-067606>

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, 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 release of CYB003 12-week durability data in Q1 2024; progression to Phase 3 development of CYB003 in early 2024; recruitment for a CYB003 Phase 3 study and commencement of the phase 3 study in Q1 2024; submission of topline data to the FDA for an end of Phase 2 meeting in early 2024; topline Phase 1 data for CYB004 and SPL028 expected in early 2024; commencement of a Phase 2 study of the Company's proprietary novel dDMT compounds in patients with generalized anxiety disorder in early 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 six month periods ended September 30, 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 Neo Exchange Inc. 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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