

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 September, 2023.

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: September 21, 2023

By: /s/ Doug Drysdale

Name: Doug Drysdale

Title: Chief Executive Officer

EXHIBIT INDEX

99.1 [News Release dated September 21, 2023](#)



Cybin Completes Enrollment in Phase 2 Study of CYB003 in Major Depressive Disorder

- Phase 2 topline efficacy data for CYB003 on track for Q4 2023, followed by U.S. Food and Drug Administration ("FDA") submission of CYB003 Phase 1/2 data for pivotal studies -

- Breakthrough Therapy designation anticipated in late 2023, subject to FDA approval -

- Previously announced acquisition of Small Pharma Inc. expected to close in Q4 2023, creating an international clinical-stage leader in novel psychedelic therapeutics -

- Multinational operations support potential scaling to Phase 3 development of CYB003 in early 2024 -

TORONTO, CANADA – September 21, 2023 – [Cybin Inc.](#) (NYSE American:CYBN) (NEO:CYBN) ("**Cybin**" or the "**Company**"), a clinical-stage biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative psychedelic-based treatment options, is pleased to announce that it has completed enrollment in its Phase 2 study of CYB003, a proprietary deuterated psilocybin analog program being developed for the potential treatment of major depressive disorder ("MDD"). All participants in the final cohort have received at least one dose (placebo or 16mg of CYB003) with several second doses already administered, and no serious adverse events observed in participants. To date, CYB003 has demonstrated a favorable safety and tolerability profile at all doses evaluated in the five completed cohorts (1mg, 3mg, 8mg, 10mg, and 12mg). The Company expects to complete dosing the final cohort in early Q4 2023.

The Company has initiated plans to scale the CYB003 program to a potential Phase 3 study in early 2024, including a streamlined EMBARK^{CT} facilitator training program, partnering with a global contract research organization, and preparing for Good Manufacturing Practice ("GMP") production of CYB003 capsules. The CYB003 program is supported by a recently granted U.S. patent covering composition of matter claims until 2041. Further, the Company anticipates potential Breakthrough Therapy designation, subject to FDA approval, in Q4 2023.

“The completion of enrollment in our Phase 2 CYB003 study is a significant milestone for Cybin that brings us closer than ever to understanding the potential antidepressant effects and clinical advantages of CYB003. We look forward to reporting topline efficacy results later this year, which will inform our plans for upcoming pivotal studies,” said Doug Drysdale, Chief Executive Officer of Cybin. “Additionally, we have made substantial progress in preparing to scale to a multinational Phase 3 trial of CYB003 early next year and were recently granted a composition of matter patent further securing intellectual property protection for this important program.”

“Looking ahead, we expect to close our acquisition of Small Pharma Inc. in Q4 2023, forming the most robust intellectual property portfolio in the sector and enhancing the combined company’s capabilities to bring these novel therapeutics through clinical development and to people in need,” concluded Drysdale.

About the Phase 1/2 CYB003 Trial

The Phase 1/2 trial is a randomized, double-blind, placebo-controlled study evaluating CYB003 in participants with moderate to severe MDD and in healthy volunteers. Healthy volunteers receive two administrations (placebo/active and active/active) one week apart, and measures of psychedelic effect are assessed after each dose. Participants with MDD receive two administrations (placebo/active and active/active) three weeks apart and response/remission are assessed three weeks after each dose. MDD participants in the trial that are currently being treated with antidepressants are allowed to remain on their antidepressant medication.

The study will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics, and psychedelic effect of ascending oral doses of CYB003. In participants with MDD, the trial will also assess rapid onset of antidepressant effect on the day of dosing, using the Montgomery-Asberg Depression Rating Scale (“MADRS”) and evaluate the incremental benefit of a second dose of CYB003 when administered at Week 3. An optional period of assessment will help determine the durability of treatment effect out to 12 weeks. The study is listed on ClinicalTrials.gov under Identifier: NCT05385783.

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 anticipated results and potential of the Company’s CYB003 Phase 1/2a trial; timing in respect of completion of CYB003 dosing; the Company’s plan to report Phase 2 safety and efficacy data from its CYB003 program in late 2023; progression to Phase 3 development of CYB003 in early 2024; the possibility of obtaining FDA Breakthrough Therapy designation for CYB003, and the timing for receiving such designation; timing of the Company’s submission to the FDA of its CYB003 Phase 1/2a data for pivotal studies; the anticipated timing for the closing of the Small Pharma Inc. acquisition; and statements regarding 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 months ended June 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 SEDAR+ at 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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