

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 August, 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: August 17, 2023

By: /s/ Doug Drysdale

Name: Doug Drysdale

Title: Chief Executive Officer

EXHIBIT INDEX

99.1 [News Release dated August 17, 2023](#)



Cybin Prepares for GMP Manufacturing of CYB003 Capsules for Phase 3 Trial

- CYB003 capsule formulation is designed to be stable, dose flexible, patient-friendly and commercially scalable -

- Shipments of CYB003 capsules to clinical sites expected in Q1 2024 -

- Recently granted U.S. patent covers composition of matter claims and treatment methods in support of the Company's CYB003 program until 2041 -

TORONTO, CANADA – August 17, 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, today announced that it has initiated preparations for good manufacturing practices (“GMP”) production of a capsule formulation of CYB003, its proprietary deuterated psilocybin analog in development for the potential treatment of Major Depressive Disorder (“MDD”).

The Company has developed a robust solid dosage capsule form of CYB003 designed to be stable, dose flexible, patient-friendly, and commercially scalable, to be evaluated in a potential Phase 3 trial. In its current Phase 2 MDD study, CYB003 dosing is underway in the final cohort. Topline efficacy data is expected in Q3/Q4 of 2023, after which the Company intends to submit data to the U.S. Food and Drug Administration (“FDA”) for an end of Phase 2 meeting.

“The development of a capsule formulation of CYB003 represents a meaningful advancement toward a commercially viable and more convenient dosing option that is potentially suitable for a future Phase 3 trial. We are very pleased with the progression of our CYB003 program in MDD thus far. Preparations for GMP manufacturing of CYB003 capsules continue to build on our efforts to progress an improved treatment option for people with major depressive disorder,” said Doug Drysdale, Chief Executive Officer of Cybin. “Coupled with our partnership with Worldwide Clinical Trials, a global CRO with deep expertise in psychedelic clinical trials, and the development of EMBARK^{CT}, a scalable model of our psychedelic facilitation program, these

efforts are a testament to our clinical execution and capabilities at each step along our development pathway.”

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 Twitter, 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 plans to provide topline clinical data readouts from the CYB003 Phase 2a study in 2023; the expected timeline for the shipment of CYB003 capsules to clinical sites in Q1 2024; anticipated timeline for submission of data to the FDA; and the Company’s plans to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health conditions.

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 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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