



Cybin Acquires DMT Clinical Study from Entheon Biomedical

June 7, 2022

-- Acquisition of largest Phase 1 DMT study conducted to date is expected to accelerate CYB004 program timeline by nine months --

-- Phase 1 study evaluating pharmacokinetics/pharmacodynamics of DMT currently underway and will inform clinical path forward --

TORONTO--(BUSINESS WIRE)-- [Cybin](#) Inc. ([NEO:CYBN](#)) (NYSE American:CYBN) (**Cybin** or the **Company**), a biopharmaceutical company focused on progressing “Psychedelics to Therapeutics™”, today announced that, through its wholly-owned subsidiary Cybin IRL Limited, it has entered into an agreement to acquire a Phase 1 N,N-dimethyltryptamine (“DMT”) study (the “Acquisition”) from Entheon Biomedical Corp. (CSE: ENBI) (OTCQB: ENTBF) (FSE: 1XU1) (“Entheon”) to accelerate the clinical development path for CYB004, Cybin’s proprietary deuterated DMT molecule for the potential treatment of anxiety disorders.

The Phase 1 EBRX-101 study, now named CYB004-E, is being conducted in the Netherlands at the Centre for Human Drug Research, a leading independent foundation specializing in innovative early-stage clinical drug research, in 50 healthy volunteers who smoke tobacco – making it the largest Phase 1 DMT clinical study conducted to date. Pending the close of the Acquisition, the CYB004-E study is expected to yield essential safety and dosing optimization data and will replace Cybin’s planned pilot study for CYB004 that was expected to commence in the third quarter of 2022. Entheon will continue to support the CYB004-E study and act as external consultants to Cybin.

“The most precious commodity in drug development is time and acquiring this robust Phase 1 study already underway potentially accelerates the CYB004 development program by approximately nine months. The PK findings from the CYB004-E study should also help to inform the clinical path forward for this innovative and proprietary molecule,” said Doug Drysdale, Chief Executive Officer of Cybin. “This transaction also provides Cybin with access to a world-class research foundation and the privilege to work with the Entheon team, who offer a wealth of knowledge and expertise in this psychedelic class.”

The purchase price of the Acquisition is \$1,000,000 (CAD), a portion of which will be a deposit with the balance payable on closing of the Acquisition. Up to an additional \$480,000 (CAD) is payable for consulting services to be provided by Entheon for up to twelve months following the closing of the Acquisition. Pursuant to the Acquisition the Company will also enter into a data license agreement with Entheon that will permit Entheon to access certain data to support the Entheon IQ program. The Company expects the Acquisition to close within 30 days, subject to the completion of certain conditions and obtaining all necessary approvals.

“With our recent IND filing for CYB003, we are quickly becoming a multi-program clinical-stage company with four sponsored human trials underway in 2022. This is especially meaningful to our work to bring our innovative psychedelic-based therapies to people in need as quickly as possible. This is a truly exciting time for Cybin,” concluded Drysdale.

About the CYB004-E Study

The CYB004-E study is an adaptive, randomized, double-blind, placebo-controlled, single ascending dose study to evaluate the safety, pharmacokinetics (“PK”) and pharmacodynamics (“PD”) of a target-controlled intravenous infusion of DMT in healthy smokers.

Primary Objectives:

- Evaluate the safety of increasing doses of a single dose continuous DMT infusion over 90 minutes;
- Characterize the PK of a single dose DMT administered continuously over 90 minutes;
- Characterize the PD of a single dose DMT administered continuously over 90 minutes; and
- Establish the minimum DMT dose required to produce a psychedelic effect.

Pending results from the CYB004-E study, Cybin plans to evaluate CYB004 delivered via intravenous (“IV”) and via inhalation to determine the clinical path forward. Based on preclinical results reported by Cybin in April 2022, inhaled CYB004 demonstrated:

- Approximately 2000% improved bioavailability compared with orally administered DMT, which is known to have limited to no oral bioavailability;
- Approximately 41% improved bioavailability compared with inhaled DMT;
- Approximately 300% longer duration of effect when compared with IV DMT, indicating potential to extend therapeutic

window; and

- Rapid onset of effect and similar low variability equivalent to IV DMT.

CYB004 is a new chemical entity for which a patent was issued by the U.S. Patent and Trademark Office in February 2022. The allowed claims include a range of deuterated forms of DMT and 5-MeO-DMT. The composition of matter patent is expected to expire in 2041 before consideration of any patent term extensions.

About Cybin

Cybin is a leading ethical biopharmaceutical company, working with a network of world-class partners and internationally recognized scientists, on a mission to create safe and effective therapeutics for patients to address a multitude of mental health issues. Headquartered in Canada and founded in 2019, Cybin is operational in Canada, the United States, the United Kingdom, the Netherlands and Ireland. The Company is focused on progressing Psychedelics to Therapeutics by engineering proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health disorders.

Cautionary Notes and Forward-Looking Statements

Certain statements in this press release constitute forward-looking information. All statements other than statements of historical fact contained in this press release, including, without limitation, statements regarding Cybin's future, strategy, plans, objectives, goals and targets, and any statements preceded by, followed by or that include the words "believe", "expect", "aim", "intend", "plan", "continue", "will", "may", "would", "anticipate", "estimate", "forecast", "predict", "project", "seek", "should" or similar expressions or the negative thereof, are forward-looking statements. Forward-looking statements in this news release include statements regarding the Company's proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens to potentially treat psychiatric disorders, the anticipated timeline for closing the Acquisition, the Company's expectation that the Acquisition will accelerate the CYB004 timeline, and the Company's expectations and objectives regarding the results of the study.

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 COVID-19 pandemic 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 the Company's management's discussion and analysis for the period ended December 31, 2021 and the Company's listing statement dated November 9, 2020, which are available under the Company's profile on www.sedar.com 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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