Cybin Inc. Reports First Quarter Financial Results and Recent Business Highlights

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TORONTO--(BUSINESS WIRE)-- Cybin Inc. (NEO:CYBN) (NYSE American:CYBN) ("**Cybin**" or the " **Company**"), a biopharmaceutical company focused on progressing "Psychedelics to Therapeutics ™", today reported unaudited financial results for its first quarter ended June 30, 2022 and recent business highlights.

"Looking back at the last 12 months, we have made positive progress toward our goal of advancing psychedelics to therapeutics. In that time, we have moved from the lab to the clinic where we now have two major development programs underway," said Doug Drysdale, Chief Executive Officer of Cybin.

"Our lead candidate CYB003 is the first novel psilocybin analog to be evaluated in a Phase 1/2a trial for the treatment of major depressive disorder. Enrollment has commenced and interim pharmacokinetic and safety data is expected at the end of the year.(1) Our Phase 1 CYB004-E study to evaluate the safety, pharmacokinetics and pharmacodynamics of a target-controlled intravenous infusion of DMT in healthy tobacco smokers is also underway. This is the largest Phase 1 DMT study to date and has the potential to yield important information as we look to potentially create improved treatment options for anxiety disorders," continued Drysdale.

Recent Business and Pipeline Highlights:

- **Initiated enrollment for its first-in-human Phase 1/2a trial of CYB003 in major depressive disorder ("MDD").** The Company announced that it received a "may proceed letter" and Investigational New Drug Application clearance from the U.S. Food and Drug Administration (the "**FDA**") for its Phase 1/2a study in June 2022. The Phase 1/2a trial is a randomized, double-blind, placebo-controlled study evaluating up to two doses of CYB003 in approximately 32 patients with moderate to severe MDD. The Company has partnered with Clinilabs Drug Development Corporation, a full-service contract research organization with expertise in central nervous system drug development, to conduct this Phase 1/2a trial. CYB003 is designed to potentially address the challenges and limitations of oral psilocybin. Based on preclinical data, CYB003 achieved less variability in plasma levels, faster onset of action, and shorter duration of effect.
- **Completed the acquisition of a Phase 1 DMT study from Entheon Biomedical Corp.** The CYB004-E study, which is ongoing at the Centre for Human Drug Research in the Netherlands, is the largest Phase 1 DMT study conducted to date. The study is assessing the pharmacokinetics and pharmacodynamics of intravenous DMT in 50 healthy tobacco smokers, and is anticipated to provide safety and dosing data to inform the clinical development plan for CYB004. In preclinical studies, CYB004 demonstrated key advantages over intravenous and inhaled DMT, including longer duration and rapid onset of effect, improved bioavailability, and low variability.
- **Continued to build the Company's intellectual property portfolio, with 1 patent issued and 19 patents pending across six patent families.** The Company's IP portfolio includes a United States Patent and Trademark Office patent covering certain deuterated forms of DMT and 5-MeO-DMT. This patent protects CYB004 as a putative new chemical entity. In addition, an international patent application was published by the World Intellectual Property Organization covering inhalation delivery methods for multiple psychedelic molecules.
- **Completed more than 200 preclinical studies to date, supporting the Company's growing portfolio of proprietary psychedelic molecules.** This highlights Cybin's dedication to researching and developing potential psychedelic treatments for patients in need. To date, the Company has developed over 50 novel compounds, and continues to advance preclinical work on its proprietary molecules being developed for the potential treatment of various mental health conditions.

Upcoming Pipeline and Strategic Milestones:

CYB003: Deuterated psilocybin analog for the potential treatment of MDD and AUD

- The Company plans to report interim safety and PK data from the Phase 1/2a study at the end of calendar year 2022.(1)

CYB004: Deuterated DMT for the potential treatment of anxiety disorders

- The CYB004-E Phase 1 study is currently underway, and is evaluating DMT in 50 healthy volunteers who smoke tobacco. The Company expects the last subject visit by November, and to complete the Phase 1 study in the first quarter of calendar 2023.(1)

CYB005: Phenethylamine derivative for the potential treatment of neuroinflammation

- The Company expects to report preclinical data for CYB005 in the second half of calendar year 2022, at which time the Company expects to nominate a candidate and complete its assessment of the potential path forward for this candidate, including whether to develop internally or by way of a potential third party partnership.(2)

Kernel Flow®

- Cybin and its partner Kernel expect to report data from a Phase 1 feasibility study evaluating brain activity following ketamine administration and the participant's experience wearing the Flow headset in the fourth quarter of calendar year 2022. Results from the study will determine the next steps forward for this important program.(3)

"Our commitment to finding safe and more effective treatments across the spectrum of mental health conditions has never been greater. Looking ahead, we are especially encouraged by the support that the healing potential of psychedelics continues to receive by many governmental and mainstream organizations. This is an exciting time for Cybin and for the industry as a whole as we move even closer to bringing potential psychedelic therapies to people in need," concluded Drysdale.

First Quarter Financial Highlights:

- Cash and cash equivalents totaled to C$42.5 million as of June 30, 2022.
- Cash-based operating expenses totaled C$11.2 million for the quarter ended June 30, 2022, of which C$1.1 million were one-time, non-recurring costs. Non-cash expenses totaled C$1.9 million for a net loss of C$13.1 million.
- Cash flows used in operating activities were C$11.1 million for the quarter ended June 30, 2022 of which C$1.1 million were one-time, non-recurring costs.

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 news release related 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 of the Company's CYB003 Phase 1/2a trial, statements regarding the Company's Phase 1 DMT clinical study for CYB004-E and anticipated results, the Company's statements regarding its preclinical data for CYB005 and partnering opportunities, statements regarding the Phase 1 Flow feasibility study and expected results, and anticipated results 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 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 year ended March 31, 2022, and the Company's annual information form for the year ended March 31, 2022, 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 FDA, 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.

Notes:

1. There is no assurance that these timelines will be met. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company.
2. Anticipated timelines and spending regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date. This statement is based on the following material factors and assumptions: (a) the Company assumes it will enter into a contract with a licensed third-party vendor to undertake extensive preclinical characterization of target molecules on the Company's behalf; (b) the Company anticipates to complete a number of animal models and the completion of Absorption, Distribution, Metabolism, and Excretion profiles; and (c) the Company assumes to enter into third party agreements in order to complete a range of additional preclinical programs including but not limited to dose-ranging studies in multiple animal species, toxicity studies in multiple animal species, genotoxicity studies, teratogenicity studies, along with neuropharmacological, pulmonary, and cardiovascular profiling before the final selection of drug candidates for entry into human trials. As of the date hereof, it has not yet completed the aforementioned items. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.
3. There is no assurance that these timelines will be met. Anticipated timelines regarding sponsorships are based on reasonable assumptions informed by current knowledge and information available to the Company from sponsorship partners.

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