



PsyBio Therapeutics Develops Commercial Purification Process for Second Generation Psycho-Targeted Compound

PsyBio Therapeutics Further Expands Scalable Manufacturing Process Development

OXFORD, OH and COCONUT CREEK, FL, May 16, 2022 – PsyBio Therapeutics Corp. (TSXV: PSYB) (OTCQB: PSYBF) ("**PsyBio**" or the "**Company**"), a fully integrated and intellectual property driven biotechnology company developing novel, bespoke psychoactive medicinal candidates targeting the potential treatment of mental health challenges, neurological disorders and other human health conditions, today reported that it has achieved a commercially scalable purification method for one of its second generation compounds. This manufacturing process achievement is expected to enable the commercial scale purification of bioreactor produced products utilizing state of the art manufacturing methodology to further expand PsyBio's portfolio of compounds that can be more readily and rapidly developed than competitive methods. This purification process methodology is a necessary component for the Chemistry, Manufacturing and Controls section ("CMC") for this second-generation candidates Investigational New Drug ("IND") application with the US Food and Drug Administration ("FDA").

"Developing adequate and scalable methodology for the purification of pipeline compounds will allow PsyBio to enable bench scale technology to be adapted to modern biotechnological production efficiency. This technology is necessary to produce reliable and predictable purity which allows more rapid development of large scale lots of material," stated Michael Spigarelli, MD, PhD, MBA, PsyBio's Chief Medical Officer. "This is expected to facilitate effective *in vitro* and *in vivo* testing, moving towards additional clinical trials for psycho-targeted therapeutics intended to potentially improve mental and neurological health."

PsyBio retains the global, exclusive, and perpetual right to license a platform technology enabling rapid generation of tryptamines and related compounds through a biosynthetic process using genetically modified bacteria and has demonstrated the ability to manufacture one of its first promising therapeutic candidates at commercial scale. Commercial purification process development furthers the ability to manufacture compounds with predictable and reproducible purity.

“PsyBio continues to make significant progress in the manufacturing arena, developing effective and scalable techniques to enhance the ability to produce an ever-growing number of psycho-targeted therapeutic candidates in a rapid and highly cost-efficient manner,” stated Evan Levine, PsyBio’s Chief Executive Officer. “The development of this type of manufacturing processes improves PsyBio’s capability to develop and rapidly manufacture novel therapeutic agents. PsyBio remains one of the only biotechnology companies in the psychoactive therapeutic industry developing their own compounds as most of the landscape appears to rely on third party providers.”

About PsyBio Therapeutics Corp.

PsyBio is an intellectual property driven biotechnology company developing new, bespoke, fully approved, psycho-targeted therapeutics to potentially improve mental and neurological health. The team has extensive experience in drug discovery based on synthetic biology and metabolic engineering as well as clinical and regulatory expertise progressing drugs through human studies and regulatory protocols. Research and development is currently ongoing for naturally occurring psychoactive tryptamines originally discovered in different varieties of hallucinogenic mushrooms, other tryptamines and phenethylamines and combinations thereof. The Company utilizes a bio-medicinal chemistry approach to therapeutic development, in which psychoactive compounds can be utilized as a template upon which to develop precursors and analogs, both naturally and non-naturally occurring, specifically because they are already known to have an effect within the brain.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that constitute "forward-looking information" ("**forward-looking information**") within the meaning of applicable Canadian securities legislation. All statements, other than statements of historical fact, are forward-looking information and are based on expectations, estimates and projections as at the date of this news release. Any statement that discusses predictions, expectations, beliefs, plans, projections, objectives, assumptions, future events or performance (often but not always using phrases such as "expects", or "does not expect", "is expected", "anticipates" or "does not anticipate", "plans", "budget", "scheduled", "forecasts", "estimates", "believes" or "intends" or variations of such words and phrases or stating that certain actions, events or results "may" or "could", "would", "might" or "will" be taken to occur or be achieved) are not statements of historical fact and may be forward-looking information. Forward looking-statements in this press release include statements regarding: the impact of this manufacturing process achievement on commercial scale purification; the impact of this

manufacturing process achievement on the CMC section of PsyBio's IND application with the FDA; PsyBio's ability to develop compounds more readily and rapidly than competitive methods; PsyBio's plans for filing IND applications with the FDA; the impact of this new manufacturing on potential *in vitro* and *in vivo* testing; PsyBio's plans to move towards additional clinical trials for psycho-targeted therapeutics intended to potentially improve mental and neurological health; PsyBio's ability to develop novel therapeutic agents; PsyBio's ability to develop novel formulations to potentially treat neurologic and psychologic conditions and other disorders; PsyBio's ability to launch clinical trials; PsyBio's ability to build its intellectual property portfolio of novel drug candidates; PsyBio's ability to achieve cost competitive synthesis with reduced environmental impact over current production methods; and PsyBio's ability to move target candidates into scaled commercial manufacturing and regulatory application.

In disclosing the forward-looking information contained in this press release, the Company has made certain assumptions, including that: this manufacturing process will enable commercial scale purification of bioreactor produced products; this manufacturing process will have a positive impact on potential *in vitro* and *in vivo* testing; this manufacturing process will have a positive impact on progress toward the filing of IND applications with the FDA; PsyBio will be successful in protecting its intellectual property; PsyBio will be successful in discovering new valuable target molecules; PsyBio will be successful in obtaining IND applications and will be able to obtain all necessary approvals for clinical trials; PsyBio will be successful in launching clinical trials; the results of preclinical safety and efficacy testing will be favorable; PsyBio's technology will be safe and effective; a confirmed signal will be identified in PsyBio's selected indications; and that drug development involves long lead times, is very expensive and involves many variables of uncertainty. Although the Company believes that the expectations reflected in such forward-looking information are reasonable, it can give no assurance that the expectations of any forward-looking information will prove to be correct. Known and unknown risks, uncertainties, and other factors which may cause the actual results and future events to differ materially from those expressed or implied by such forward-looking information. Such factors include, but are not limited to: compliance with extensive government regulations; domestic and foreign laws and regulations adversely affecting PsyBio's business and results of operations; decreases in the prevailing process for psilocybin and nutraceutical products in the markets in which PsyBio operates; the impact of COVID-19; and general business, economic, competitive, political and social uncertainties. Accordingly, readers should not place undue reliance on the forward-looking information contained in this press release. Except as required by law, the Company disclaims any intention and assumes no obligation to update or revise any forward-looking information to reflect actual results, whether as a result of new

information, future events, changes in assumptions, changes in factors affecting such forward-looking information or otherwise.

PsyBio makes no medical, treatment or health benefit claims about PsyBio's proposed products. The FDA or other similar regulatory authorities have not evaluated claims regarding psilocybin and other next generation psychoactive compounds. The efficacy of such products has not been confirmed by FDA-approved research. There is no assurance that the use of psilocybin and other psychoactive compounds can diagnose, treat, cure, or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. PsyBio has not conducted clinical trials for the use of its intellectual property. Any references to quality, consistency, efficacy and safety of potential products do not imply that PsyBio verified such in clinical trials or that PsyBio will complete such trials. If PsyBio cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the PsyBio's performance and operations.

The TSX Venture Exchange (the "TSXV") has neither approved nor disapproved the contents of this news release. Neither the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

SOURCE PsyBio Therapeutics Corp.

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