Brii Biosciences Limited
腾盛博药生物科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2137)

VOLUNTARY ANNOUNCEMENT
BUSINESS UPDATE

This announcement is made by the board of directors (the "**Board**") of Brii Biosciences Limited (the "**Company**") on a voluntary basis.

The Board is pleased to announce the topline results from a Phase 1 study evaluating the Company's long-acting, single-injection therapy, BRII-296, in the development for the treatment of postpartum depression ("**PPD**"). These data show that a single treatment via intramuscular ("**IM**") injection of 600 mg of BRII-296 achieved dose linearity, early drug absorption, gradual and extended-release profiles without the need for dose titration or tapering, providing confidence that this dose has potential to achieve clinical efficacy in the treatment of PPD. The selected dose regimen will be evaluated in a Phase 2 clinical trial that is expected to begin this year.

BRII-296 acts as a novel gamma-aminobutyric acid A receptor positive allosteric modulator with a unique long-acting formulation that does not require cessation of breastfeeding and enables the drug to be effective for weeks after the patient received the injection. It is designed to provide a rapid, profound and sustained reduction in depressive symptoms of PPD and may offer substantial and clinically meaningful advantages over the currently available treatment options for PPD.

"We are encouraged by the possibility of providing a novel treatment option to around 900,000 people in the United States of America affected by postpartum depression each year in which the current standard of care is suboptimal which often requires hospitalization, repeating therapies and daily doses of treatment," said Dr. Ji Ma, Ph.D., Vice President of Preclinical Development and Clinical Pharmacology of the Company and the lead author. "These data reinforce the potential of BRII-296 to redefine the PPD treatment landscape by providing a one-time, outpatient therapy that may effectively treat a range of depressive symptoms while maintaining a favorable safety and tolerability profile, including minimal exposure to breastfed infants."

"Initial results from this study are an important step forward as we continue to advance the development of BRII-296 in a robust and thoughtfully designed Phase 2 clinical study later this year that will incorporate fundamental patient experiences and preferences," said Dr. Aleksandar Skuban, M.D., Central Nervous System Diseases Therapy Area Head of the Company. "This comprehensive approach to drug development is critical in areas such as PPD where there are often considerable barriers to accessing care, partly because of the wide-reaching social stigmas and a lack of disease awareness. This program reinforces the Company's dedication to operate at the intersection of scientific innovation and patient insights in order to inform the full spectrum of strategic development in mental health conditions such as PPD as well as our broader global public health-inspired pipeline."

Data from healthy subjects in cohorts 1-15 were presented in a poster, titled Safety, Tolerability, and Pharmacokinetics of BRII-296, An Extended-Release Injectable Aqueous Suspension Formulation of Brexanolone in Healthy Adult Subjects, at the International Marcé Society Conference taking place in London, United Kingdom, from September 19 to 23, 2022. The full Phase 1 dataset will be presented at a scientific conference later this year.

About BRII-296 Phase 1 Trial

The completed open-label, Phase 1, single ascending dose study assessed the safety, tolerability and pharmacokinetics of BRII-296 as a single-injection treatment option for PPD in 116 subjects enrolled across 16 cohorts. Three formulation concentrations (100 mg/mL, 200 mg/mL and 300 mg/mL) were administered via one or more IM injections to healthy adults at total dose levels of 30 mg, 75 mg, 100 mg, 200 mg, 300 mg and 600 mg. In addition, oral prophylactic treatment, or local steroid administration with BRII-296 (Depo Medrol via co-injection or admix) were evaluated to manage local injection site reactions ("**ISRs**"). The local steroid administration was shown in the study to effectively manage ISRs.

Of the 116 subjects, 98 subjects reported treatment emergent adverse events ("**TEAEs**"), with the majority considered drug-related and attributed to ISRs. Most ISRs were mild to moderate in severity and none lead to premature discontinuation from the study. There was no life threatening TEAEs, TEAEs leading to premature discontinuation of study, serious adverse events, or deaths.

Cautionary Statement: There is no assurance that BRII-296 will ultimately be successfully developed or marketed by the Company. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company. When in doubt, shareholders of the Company and potential investors are advised to seek advice from professional or financial advisers.

By order of the Board
Brii Biosciences Limited
Dr. Zhi Hong
Chairman

Hong Kong, September 26, 2022

As at the date of this announcement, the Board comprises Dr. Zhi Hong as executive director; Mr. Robert Taylor Nelsen and Dr. Axel Bouchon as non-executive directors; and Dr. Martin J Murphy Jr, Ms. Grace Hui Tang, Mr. Yiu Wa Alec Tsui, Mr. Gregg Huber Alton and Dr. Taiyin Yang as independent non-executive directors.