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 progress against the Company's strategic clinical development priorities, including various updates across the Company's pipeline of infectious disease and central nervous system disease candidates.

"We continue to progress clinical development of our two lead pipeline programs for a novel functional cure for hepatitis B viral ("**HBV**") infection in China and a potential first-of-its-kind treatment for postpartum depression ("**PPD**") in the U.S.," said Dr. Zhi Hong, Ph.D., the Chairman and the Chief Executive Officer of the Company. "These recent advancements in HBV and PPD provide a sharper focus for our China and U.S. teams, respectively, and further exemplify our differentiated approach to pursue curative or single treatment options in two large and important disease areas. We look forward to continuing to foster strategic collaborations and harness our proven development capabilities as we advance our pipeline of therapeutic candidates for patients."

Set out below are the updates of the Company's lead clinical programs and additional pre-clinical and clinical development.

Updates of the Company's Lead Clinical Programs

Hepatitis B Virus

The Company is building a novel and first-in-class clinical portfolio of HBV therapeutic candidates alongside our strategic partners that may be used in various combinations to improve the probability of achieving a high rate of functional cure for each subpopulation of HBV patients in China. While HBV is one of the world's most significant infectious disease threats, China has the largest prevalence of HBV in the world, with 87 million people impacted by this disease.

- Patients have completed the treatment in the Company's ongoing Phase 2 multi-regional clinical trial combination study of BRII-179 (VBI-2601) and BRII-835 (VIR-2218). The abstract highlighting the interim safety and efficacy data from this study has been accepted for oral presentation at the 32nd Conference of the Asian Pacific Association for the Study of the Liver, taking place in Taipei, Taiwan, from February 15 to 19, 2023.

- In December 2022, the Company completed the patient enrollment in part 1 of a Phase 2 combination trial evaluating the addition of BRII-179 (VBI-2601) in chronic HBV patients already receiving pegylated interferon alpha ("**PEG-IFN-α**") and nucleotide/nucleoside reverse transcriptase inhibitors treatment. Topline results are expected in the third quarter of 2023.

- The Company's strategic development partner, Vir Biotechnology, Inc. ("**Vir**"), shared preliminary data from an ongoing Phase 2 trial of combination of BRII-835 (VIR-2218) with PEG-IFN-α, which demonstrated that approximately 30% of patients with chronic HBV infection achieved hepatitis B surface antigen seroclearance with hepatitis B surface antibody seroconversion by the end of the treatment with no new safety signals. The results were presented in an oral session at The Liver Meeting® of the American Association for the Study of Liver Diseases.

- Initial data from Part B of Vir's ongoing Phase 2 Monoclonal Antibody siRNA Combination against Hepatitis B trial are expected in the second half of 2023 and will evaluate BRII-835 (VIR-2218) and BRII-877 (VIR-3434) together and in triple combination with PEG-IFN-α, including determining dose and length of treatment.

Postpartum Depression

The Company is developing BRII-296 as a first-of-its-kind one-time injection therapeutic candidate with the potential to expand the PPD treatment landscape for patients in the U.S., where one in seven new mothers are impacted by this condition.

- The Company recently participated in a Type C meeting with the U.S. Food and Drug Administration ("**U.S. FDA**") at which it received productive feedback and guidance regarding the Company's Investigational New Drug ("**IND**") application for BRII-296. Following this discussion, the Company is preparing to initiate its Phase 2 study of BRII-296 for the treatment of PPD in early 2023.

- In September 2022, the Company announced positive topline results from its Phase 1 study of BRII-296 with data that demonstrated a single administration of the investigational therapy at 600 mg delivered a favorable pharmacokinetic ("**PK**") profile and was safe and well-tolerated in healthy subjects. Furthermore, early feedback from physicians and patient communities are very positive and this reinforces the potential for a first-of-its-kind single-injection treatment option for PPD.

Additional Pre-Clinical and Clinical Development Updates

Human Immunodeficiency Virus ("HIV") Infection

- Based on PK data from a completed Phase 1 study, the Company has made the decision to discontinue the development of BRII-778, which was being evaluated as part of a potential long-acting combination therapy for HIV infection. The Company is exploring partnership opportunities to continue developing BRII-732 as part of a potential oral, once-weekly, long-acting combination treatment option for HIV type 1 patients.

- In October 2022, the Company presented positive Phase 1 data showing that BRII-732 demonstrated an acceptable safety and tolerability profile, as well as a favorable and linear PK profile that achieved therapeutic targets in healthy volunteers, reinforcing its potential as an once-weekly oral therapy for the treatment and prevention of HIV infections.

- The Company recently received notification that the U.S. FDA has lifted the clinical hold on the Company's planned Phase 1 study to investigate a lower oral dose of once-weekly BRII-732.

Multi-Drug Resistant/Extensive Drug Resistant Gram-Negative Bacteria Infections

- BRII-672 has the potential to be the first oral treatment option for complicated urinary tract infections targeting gram-negative bacteria resistant to carbapenem. In December 2022, the first pre-IND was submitted to the National Medical Products Administration (the "**NMPA**") of China seeking regulatory guidance on a development plan for BRII-672 in China.

- BRII-693 has a highly differentiated safety and efficacy profile to address the most difficult-to-treat *Acinetobacter baumannii* and *Pseudomonas aeruginosa* infections resistant to carbapenem. The Company plans to submit a pre-IND to the China's NMPA in the first quarter of 2023.

- Preclinical data and interim Phase 1 clinical results for BRII-636, BRII-672 and BRII-693 were presented at Infectious Disease Week in October 2022.

Nontuberculosis Mycobacteria Lung Disease

- The Company's strategic partner, AN2 Therapeutics, Inc., expects to complete the enrollment in the Phase 2 part of the pivotal Phase 2/3 clinical trial evaluating BRII-658 (epetraborole) for treatment-refractory lung disease caused by *Mycobacterium avium complex* in mid-2023 and plans to begin the enrollment of the Phase 3 portion of the trial immediately thereafter.

Coronavirus Disease 2019 ("COVID-19")

- Following the Company's commercial launch of the amubarvimab/romlusevimab combination in China, the long-acting COVID-19 neutralizing antibody therapy is being used to treat patients in China, and early feedback from physicians has been positive.

- Based on the ongoing preclinical testing, the amubarvimab/romlusevimab combination retains neutralizing activity against the major severe acute respiratory syndrome coronavirus 2 subvariants currently circulating in China, underscoring the antibody combination as an important treatment option for high risk patients in China.

Cautionary Statement: There is no assurance that BRII-179 (VBI-2601), BRII-835 (VIR-2218), BRII-877 (VIR-3434), BRII-296, BRII-732, BRII-636, BRII-672, BRII-693 or BRII-658, 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, December 27, 2022

As at the date of this announcement, the Board comprises Dr. Zhi Hong and Dr. Ankang Li as executive directors; Mr. Robert Taylor Nelsen as non-executive director; 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.