

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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)

INTERIM RESULTS ANNOUNCEMENT
FOR THE SIX MONTHS ENDED JUNE 30, 2023

The Board is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2023, together with the comparative figures for the previous year, which have been reviewed by the Audit and Risk Committee.

FINANCIAL HIGHLIGHTS

- Other income was RMB85.9 million for the six months ended June 30, 2023, representing an increase of RMB47.7 million or 124.9%, compared with RMB38.2 million for the six months ended June 30, 2022. This was mainly due to the increased bank interest income of RMB36.1 million attributable to the additional placement of time deposits with original maturity over three months and the increased income recognized from PRC government grants of RMB11.6 million.
- Research and development expenses were RMB202.2 million for the six months ended June 30, 2023, representing a decrease of RMB56.3 million or 21.8%, compared with RMB258.5 million for the six months ended June 30, 2022. The decrease was primarily due to the reduced third-party contracting cost from COVID-19 programs after the Company decided to terminate these programs.
- Administrative expenses were RMB102.8 million for the six months ended June 30, 2023, representing an increase of RMB7.3 million or 7.6%, compared with RMB95.5 million for the six months ended June 30, 2022. The increase was primarily attributable to the increase in employee headcounts and computer software fees.
- Total comprehensive expense for the six months ended June 30, 2023 was RMB104.0 million, representing a decrease of RMB113.7 million or 52.2%, compared with RMB217.7 million for the six months ended June 30, 2022. The decrease was primarily due to the increase in other income and decrease in the research and development expenses.

BUSINESS HIGHLIGHTS

Brii Bio is a commercial-stage biotechnology company dedicated to tackling major public health challenges where there is high disease burden and significant social stigma. Our approach, driven by breakthrough innovation and patient insights, has led to a robust pipeline of more than 10 therapeutic candidates, focused on infectious diseases and central nervous system diseases. As we mark our fifth year of incorporation, we take pride in our achievements and pursuit of innovation.

Moving forward, we are poised for significant corporate growth. Our key initiatives include introducing a best-in-class prophylactic vaccine to prevent hepatitis B infections in susceptible adult populations in Asia Pacific regions. Additionally, we are leading clinical development for a functional cure for broad hepatitis B patient populations in China and a potential first-of-its-kind treatment for postpartum depression and major depressive disorder in the U.S. As at the date of this announcement, our primary focus remains on these two lead clinical programs, with most of our other programs under clinical development. Leveraging the expertise of our in-house R&D team and strategic partnerships with industry leaders worldwide, we are committed to improving patient choice and access, as well as making a positive impact on public health.

In our mission to alleviate the burden of hepatitis B, we recently strengthened our core HBV assets by expanding our licensing agreements with VBI, allowing us to comprehensively address HBV disease burdens from prevention to cure. We now hold an exclusive worldwide license for BR11-179 (VBI-2601), which is increasingly supported by evidence as an important component in a combination functional cure strategy for HBV. To further complement our HBV assets, we also acquired exclusive rights from VBI to develop and commercialize PreHevbri® in Greater China and certain other Asia Pacific regions. The addition of PreHevbri® complements our existing functional cure portfolio, further advancing solutions to reduce the transmission of HBV infections across Greater China and the other Asia Pacific countries and regions.

PreHevbri® is a clinically differentiated 3-antigen adult HBV prophylactic vaccine recently approved for use in the United States, European Union/European Economic Area, United Kingdom, Canada and Israel. The Company is actively working towards the market launch of PreHevbri® in APAC markets, aiming to address the significant unmet needs for hepatitis B prevention in the vast and underserved APAC markets. The market authorization application has already been filed in Hong Kong and we are also prioritizing regions where additional trials may not be required.

Beyond vaccination, we deeply invested in developing novel combination treatments directed at specific subpopulations of HBV patients, aiming at achieving a higher functional cure rate across all HBV patient groups and improving treatment decision-making adoption. By conducting multiple trials with varying therapeutic regimens, in combination with or without standard-of-care treatments, we maximize our chances of developing a novel functional cure regimen for HBV at an accelerated pace. Our partner Vir presented compelling new data at the European Association for the Study of the Liver Congress 2023. These data underscore the potential success of achieving a best-in-class functional cure in broad HBV patient populations, reinforcing continued clinical development of BR11-835 as well as BR11-877. Notably, data from the BR11-835 in combination with PEG-IFN- α study demonstrated that robust anti-HBs antibody responses at the end of treatment were associated with sustained HBsAg loss 24 weeks post-treatment. This combination also achieved one of the highest rates of off-treatment response observed to-date, lending strong support to the hypothesis that adding an siRNA to an immunomodulator has the potential to result in functional cure rates higher than those historically seen with PEG-IFN- α alone.

Inspired by the momentum of our partner Vir's data presented on EASL Congress 2023 in June 2023, we initiated an additional BRII-835 plus PEG-IFN- α combination Phase 2 study following regulatory approvals from regulatory authorities in APAC including the IND approval from the NMPA of China in July 2023. With the first patient dosed in August 2023, the primary objective of the study is to compare the functional cure rate of BRII-835/PEG-IFN- α combination versus PEG-IFN- α alone. Furthermore, the Company intends to include patients in the study who were previously exposed to BRII-179 with documented anti-HBsAg responses. The Company believes that BRII-179 has the unique ability to distinguish the patients with significant intrinsic humoral immunity. Planning of additional studies is also underway to investigate the role of BRII-179 as a primer to elicit stronger antibody responses and in enriching patients for curative treatments such as BRII-835/PEG-IFN- α as well as other combinations in broad HBV patient populations. Carrying on the insights we acquired from all the previous studies, we step further to validate and to advance our strategy on the combination treatment regimen.

Continuing our focus on CNS programs, we are prioritizing our efforts to redefine treatment options for PPD/MDD and other anxiety and depressive disorders. We are developing a novel GABA_A PAM receptor, a first-of-its-kind long-acting formulation that can be administered as a single treatment for PPD and MDD. Additionally, we are actively working on therapeutic candidates to prevent PPD recurrence among high-risk patients and to treat anxiety and other depressive disorders. Through close collaboration with key advocacy groups in the U.S., we aim to ensure that our efforts align with the diverse needs and perspectives of patients. In the third quarter of 2023, we plan to initiate a Phase 2 proof-of-concept trial with BRII-296 in PPD patients in the U.S. BRII-296 represents a paradigm shift in patient care with the potential to provide rapid and sustained relief of depressive symptoms for new mothers. Meanwhile, subjects have already been dosed in June 2023 in our first-in-human Phase 1 study with BRII-297 for anxiety and depressive disorders in Australia.

For our HIV portfolio, we are exploring partnership opportunities to further develop BRII-732 as part of a potential oral, once-weekly, long-acting combination treatment option for HIV patients, and BRII-753 as part of a long-acting subcutaneous injection with the aim of achieving dosing intervals ranging from once monthly to every six months. Both candidates serve as ideal cornerstones for next-generation HIV therapies, presenting innovative long-acting therapy options for HIV patients.

In June 2023, we acquired exclusive global rights to the novel lipopeptide BRII-693 (previously known as QPX9003) for MDR/XDR gram-negative bacterial infections from Qpex. The unique microbiological and clinical profile of BRII-693 led us to prioritize its global development. As part of this strategic move, we returned the Greater China rights of beta-lactamase inhibitor QPX7728-based products to Qpex. We received approximately US\$24 million upon closing of the acquisition as a Qpex shareholder and the return of the QPX7728 product rights, with potential contingency payments depending on future milestone events in the U.S. As at the date of this announcement, we are actively working on our future global development plan with the IND application in China progressing on track.

Our patient-centric approach has strengthened our relationships with patients, their caregivers, and patient advocacy groups. During the Reporting Period, we continued to foster partnerships with key maternal health advocacy groups in the U.S., including sponsoring the 2023 Maternal Mental Health Forum, the 5th annual Black Maternal Mental Health Week, the 2023 Climb Out of the Darkness event, and the Mind the Gap strategic action plan by Postpartum Support International at the 36th Annual PSI Conference. These activities and industry acknowledgments have furthered our commitment to ensuring patients' voices are heard and understood throughout the discovery and development process, from R&D to commercialization.

In line with our governance strategy and an expanding global asset portfolio, we have optimized our senior executive leadership team during the Reporting Period to effectively guide our public-health-inspired programs as they advance through clinical development. Our international teams in China and the U.S. are committed to collaborative efforts, leveraging our collective strengths and expertise in both key markets and beyond. Together, we are working to make a positive impact on underserved patient populations, public health, and society as a whole.

Major Milestones Achieved as of the Date of This Announcement

Hepatitis B Virus Program (*Licensed from VBI and Vir, China team core project*)

- We have initiated an additional Phase 2 randomized and active-controlled study of BRII-835 in combination with PEG-IFN- α following regulatory approvals from regulatory authorities in APAC including the NMPA of China. First patient has been dosed in August 2023.
- We expanded our HBV portfolio in July 2023 in collaboration with VBI. Under the terms of the agreements:
 - We extended our exclusive license to worldwide markets for BRII-179 (VBI-2601).
 - We also acquired exclusive rights to develop and commercialize PreHevbri[®] in Greater China and certain other Asia Pacific countries including Australia, Indonesia, Malaysia, New Zealand, Philippines, Singapore, South Korea, Thailand and Vietnam, among others. PreHevbri[®] is a clinically differentiated 3-antigen adult HBV prophylactic vaccine recently approved for use in the United States, European Union/ European Economic Area, United Kingdom, Canada and Israel.
- We have initiated pathway mapping and are working with local regulatory authorities to expedite the market launch of PreHevbri[®] in the APAC regions, prioritizing regions where additional trials may not be required. Market authorization application for Hong Kong has already been filed, and we expect a regulatory decision in the near future.

- Vir and VBI presented data from multiple ongoing clinical studies in June 2023 at the EASL Congress™ 2023. These data suggest the potential use of anti-HBs titers as an on-treatment biomarker of off-treatment sustained response and provide more insights into developing combination treatment for a potential HBV functional cure. They further demonstrate our expertise in developing combination therapies to tackle the heterogeneity of complex diseases with a multi-prong approach, which guides us to expedite the next stage of development of novel HBV functional cure treatment regimens:
 - In follow-up data from Vir’s Phase 2 trial of combination 24 or 48 weeks of VIR-2218 (BRII-835) on top of a course of up to 48 weeks of PEG-IFN- α , 16% (5/31) of participants demonstrated sustained HBsAg loss 24 weeks after end of treatment. Anti-HBs titers greater than 500 mIU/mL at the end of treatment were associated with sustained HBsAg loss at 24 weeks after the end of treatment.
 - Data from Part A of Vir’s Phase 2 MARCH trial evaluating short treatment duration of combinations of VIR-2218 (BRII-835) and VIR-3434 (BRII-877) in chronic HBV participants demonstrated a 2.7-3.1 log₁₀ IU/mL decline in HBsAg levels and 90% of participants achieved HBsAg reduction below 10 IU/mL at the end of treatment.
 - VBI presented follow-up data from an investigator-initiated study in a subset of participants from the pivotal Phase 3 study, PROTECT, up to 3.5 years after completion of immunization with PreHevbrio®, a prophylactic 3-antigen HBV vaccine. The data demonstrated that PreHevbrio® induced T-cell responses against Pre-S1 and Pre-S2 that correlated with high anti-HBs titers. 3.5 years after completion of immunization, mean anti-HBs titers in participants vaccinated with PreHevbrio® were more than 5x higher than those vaccinated with Engerix-B (1,287 vs. 254 mIU/mL) suggesting that T-cell responses to PreHevbrio® may contribute to long lasting and strong humoral immune responses and greater durability compared with Engerix-B.
- We received an IND approval in August 2023 from the CDE of NMPA of China for the a Phase 1 clinical study of BRII-877(VIR-3434) and the trial is expected to start by the end of 2023.

Postpartum Depression and Major Depressive Disorder/Other CNS Disorders

- The Company announced in June 2023 that it had dosed the first subject in a Phase 1 clinical trial for BRII-297, a long-acting injectable being developed to treat anxiety and depressive disorders. The study, currently underway, aims to evaluate the safety, tolerability and pharmacokinetics of BRII-297 in healthy volunteers.
- Following an agreement with the U.S. FDA, we will start a Phase 2 POC study of BRII-296 in postpartum depression investigating the first-of-its-kind, long-acting, single treatment option in the third quarter of 2023.
- We are actively working to expand the clinical indications for BRII-296 and plan to initiate additional studies in the U.S. in 2024.

Human Immunodeficiency Virus Infection

- We began dosing subjects in the second quarter of 2023 in a Phase 1 study to investigate a lower oral dose of once-weekly BRII-732.
- 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 patients.

- The Company is also pursuing partnership opportunities for BRII-753 as part of a long-acting, subcutaneous injection with potential for a once monthly, once quarterly, or twice-yearly dosing combination treatment option for HIV patients.

MDR/XDR Gram-Negative Bacteria Infections

- In June 2023, we entered into definitive agreements with Qpex to acquire exclusive global rights of BRII-693 (QPX9003), expanding our existing rights in Greater China. The Company returned its exclusive rights of BRII-636 and BRII-672 in Greater China to Qpex. Brie Bio received approximately US\$24 million upon closing of the acquisition as a Qpex shareholder and the return of the QPX7728 product rights, with potential contingency payments depending on future milestone events in the U.S.
- In April 2023, we submitted a pre-IND to the NMPA of China for the development of BRII-693 in China. BRII-693 has a highly differentiated safety and efficacy profile to address the most difficult-to-treat infections due to *Acinetobacter baumannii* and *Pseudomonas aeruginosa*, including infections due to MDR/XDR isolates resistant to carbapenem antibiotics.

Nontuberculous Mycobacteria Lung Disease

- Our partner, AN2, is currently enrolling patients in its Phase 2/3 pivotal trial evaluating once-daily, oral eptetraborole (BRII-658) for treatment-refractory MAC lung disease at over 90 active clinical sites across the U.S., Japan, South Korea and Australia. AN2 expects to complete enrollment in the Phase 2 portion of the study and begin Phase 3 in September 2023 and to announce top-line data from the Phase 2 portion of the study in summer 2024.

Other Corporate Developments

- In July 2023, Dr. David Margolis was appointed as Chief Medical Officer, replacing Dr. Li Yan who departed from the Company to pursue other interests. Dr. Margolis has served as Brie Bio's Head of Infectious Diseases Therapy Area for nearly three years and will continue to fulfill his existing responsibilities in addition to his new role as Chief Medical Officer.
- In April 2023, Brie Bio published its 2022 Environmental, Social and Governance Report, outlining the Company's progress and performance towards long-term growth and success in key ESG areas. We have also been awarded an "A" rating from MSCI ESG Rating, a globally recognized assessment of a company's resilience to long-term ESG risks.
- We continued to foster partnerships with key maternal health advocacy groups to address patients' needs and preferences in the U.S., including sponsoring the 2023 Maternal Mental Health Forum, the 5th annual Black Maternal Mental Health Week, the 2023 Climb Out of the Darkness event, and the Mind the Gap strategic action plan by Postpartum Support International at the 36th Annual PSI Conference.

For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the Company's prior announcements and regulatory filings.

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the six months ended June 30, 2023

		Six months ended June 30,	
		2023	2022
	<i>Notes</i>	RMB'000	RMB'000
		(unaudited)	(unaudited)
Revenue		617	–
Other income	4	85,863	38,228
Other gains and losses, net		23,326	(34,035)
Research and development expenses		(202,175)	(258,484)
Administrative expenses		(102,823)	(95,467)
Selling and marketing expenses		(1,380)	(15,376)
Finance costs		(254)	(480)
		<hr/>	<hr/>
Loss before tax	5	(196,826)	(365,614)
Income tax expense	6	–	–
		<hr/>	<hr/>
Loss for the period		(196,826)	(365,614)
		<hr/>	<hr/>
Other comprehensive income (expense):			
<i>Items that will not be reclassified to profit or loss:</i>			
Exchange differences on translation from functional currency to presentation currency		102,567	173,492
Fair value loss on equity instrument at fair value through other comprehensive income (“FVTOCI”)		(4,484)	(22,780)
		<hr/>	<hr/>
		98,083	150,712
		<hr/>	<hr/>
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		(5,244)	(2,785)
		<hr/>	<hr/>
Other comprehensive income for the period		92,839	147,927
		<hr/>	<hr/>
Total comprehensive expense for the period		(103,987)	(217,687)
		<hr/>	<hr/>
Loss for the period attributable to:			
Owners of the Company		(189,917)	(347,587)
Non-controlling interests		(6,909)	(18,027)
		<hr/>	<hr/>
		(196,826)	(365,614)
		<hr/>	<hr/>
Total comprehensive expense for the period attributable to:			
Owners of the Company		(97,078)	(199,660)
Non-controlling interests		(6,909)	(18,027)
		<hr/>	<hr/>
		(103,987)	(217,687)
		<hr/>	<hr/>
Loss per share			
– Basic and diluted (RMB)	7	(0.26)	(0.48)
		<hr/>	<hr/>

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At June 30, 2023

	<i>Notes</i>	At June 30, 2023 RMB'000 (unaudited)	At December 31, 2022 RMB'000 (audited)
Non-current assets			
Property, plant and equipment		4,731	7,345
Right-of-use assets		7,835	12,177
Intangible assets		145,120	146,887
Financial assets at fair value through profit or loss		188,263	139,794
Equity instrument at FVTOCI		1,819	6,234
Rental deposits		2,264	2,513
		<u>350,032</u>	<u>314,950</u>
Current assets			
Deposits, prepayments and other receivables	9	107,451	77,640
Restricted bank deposits		1,945	1,875
Time deposits with original maturity over three months		2,251,426	1,806,812
Cash and cash equivalents		487,494	1,190,572
		<u>2,848,316</u>	<u>3,076,899</u>
Current liabilities			
Other payables	10	85,873	164,937
Lease liabilities		7,998	9,500
Deferred income		17,711	54,676
		<u>111,582</u>	<u>229,113</u>
Net current assets		<u>2,736,734</u>	<u>2,847,786</u>
Total assets less current liabilities		<u>3,086,766</u>	<u>3,162,736</u>
Non-current liabilities			
Lease liabilities		–	3,156
Deferred income		–	2,083
		<u>–</u>	<u>5,239</u>
Net assets		<u>3,086,766</u>	<u>3,157,497</u>
Capital and reserves			
Share capital		24	24
Share premium and reserves		3,130,768	3,194,590
Equity attributable to owners of the Company		3,130,792	3,194,614
Non-controlling interests		(44,026)	(37,117)
Total equity		<u>3,086,766</u>	<u>3,157,497</u>

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2023

1. GENERAL INFORMATION

Brii Biosciences Limited (the “Company”) was incorporated in the Cayman Islands as an exempted company with limited liability on December 8, 2017. The Company’s shares were listed on the Main Board of The Stock Exchange of Hong Kong Limited on July 13, 2021 (the “Listing”).

These condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting* issued by the International Accounting Standards Board (“IASB”) as well as the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

The directors of the Company have, at the time of approving these condensed consolidated financial statements, a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. Thus they continue to adopt the going concern basis of accounting in preparing these condensed consolidated financial statements.

2. PRINCIPAL ACCOUNTING POLICIES

These condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments, which are measured at fair value, as appropriate.

Other than additional accounting policies resulting from application of new and amendments to International Financial Reporting Standards (“IFRSs”), the accounting policies and methods of computation used in these condensed consolidated financial statements for the six months ended June 30, 2023 are the same as those presented in the Group’s annual consolidated financial statements for the year ended December 31, 2022.

Application of new and amendments to IFRSs

In the current interim period, the Group has applied the following new and amendments to IFRSs issued by the IASB, for the first time, which are mandatorily effective for the Group’s annual period beginning on January 1, 2023 for the preparation of the Group’s condensed consolidated financial statements:

IFRS 17 (including the June 2020 and December 2021 Amendments to IFRS 17)	Insurance Contracts
Amendments to IAS 8	Definition of Accounting Estimates
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction
Amendments to IAS 12	International Tax Reform-Pillar Two model Rules

Except as described below, the application of the other new and amendments to IFRSs in the current interim period has had no material impact on the Group’s financial positions and performance for the current and prior periods and/or on the disclosures set out in these condensed consolidated financial statements.

2.1 Impacts and changes in accounting policies on application of Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction

2.1.1 Accounting policies

Deferred tax is recognised on temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognised for all taxable temporary differences. Deferred tax assets are generally recognised for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilised. Such deferred tax assets and liabilities are not recognised if the temporary difference arises from the initial recognition of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit and at the time of the transaction does not give rise to equal taxable and deductible temporary differences.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 *Income Taxes* (“IAS 12”) requirements to the lease liabilities and the related assets separately. The Group recognises a deferred tax asset related to lease liabilities to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilised and a deferred tax liability for all taxable temporary differences.

2.1.2 Transition and summary of effects

As disclosed in the Group’s annual financial statements for the year ended December 31, 2022, the Group previously applied the IAS 12 requirements to assets and liabilities arising from a single transaction as a whole and temporary differences relating to the relevant assets and liabilities were assessed on a net basis. Upon the application of the amendments, the Group assessed the relevant assets and liabilities separately. In accordance with the transition provision:

- (i) the Group has applied the new accounting policy retrospectively to leasing transactions that occurred on or after January 1, 2022;
- (ii) the Group also, at January 1, 2022, recognised a deferred tax asset (to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilised) and a deferred tax liability for all deductible and taxable temporary difference associated with right-of-use assets and lease liabilities.

As a result of the application of amendments to IAS 12 *Deferred Tax related to Assets and Liabilities arising from a Single Transaction*, the Group recognised deferred tax assets and deferred tax liabilities of RMB3,044,000 and RMB3,044,000, respectively, at the end of the immediately preceding financial year, i.e. December 31, 2022, which have been offset for the purpose of presentation in the condensed consolidated statement of financial position.

3. SEGMENT INFORMATION

The Group's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer of the Group. For the purpose of resource allocation and performance assessment, the CODM reviews the overall results and financial position of the Group as a whole prepared based on the Group's accounting policies. Accordingly, the Group has only one reportable segment and only entity-wide disclosures are presented.

Geographical information

At June 30, 2023, substantially all of the Group's non-current assets (excluding financial instruments) of RMB160.0 million (December 31, 2022: RMB168.9 million) are located in the PRC and during the reporting period all of the Group's revenue from external customers are located in the PRC.

4. OTHER INCOME

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Government grants (<i>Note</i>)	39,480	27,885
Bank interest income	46,383	10,343
	<u>85,863</u>	<u>38,228</u>

Note: Government grants include the incentive and other subsidies from the PRC government which are specifically for research and development activities are recognised upon compliance with the attached conditions. In the current interim period, the Group did not receive any government grants (six months ended June 30, 2022: nil). At June 30, 2023, government grants of RMB17.7 million are recorded as deferred income and will be amortised upon compliance with the relevant conditions (December 31, 2022: RMB56.8 million).

5. LOSS BEFORE TAX

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Loss before tax for the period has been arrived at after charging:		
Depreciation of property, plant and equipment	2,614	2,614
Depreciation of right-of-use assets	4,342	4,342
Amortisation of intangible assets (included in research and development expenses)	1,559	1,358
Impairment loss recognised on intangible assets (included in other gains and losses)	5,432	—
	<u>13,947</u>	<u>8,614</u>

6. INCOME TAX EXPENSE

No provision for income tax expense has been made since the operating subsidiaries of the Company have no assessable profits for both periods.

7. LOSS PER SHARE

The calculation of the basic and diluted loss per share attributable to owners of the Company is based on the following data:

	Six months ended June 30,	
	2023	2022
	(unaudited)	(unaudited)
Loss for the period attributable to owners of the Company for the purpose of basic and diluted loss per share (<i>RMB'000</i>)	<u>(189,917)</u>	<u>(347,587)</u>
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share (<i>'000</i>)	<u>727,488</u>	<u>721,780</u>

For the six months ended June 30, 2022 and 2023, the weighted average number of ordinary shares for the purpose of basic and diluted loss per share excluded the unvested restricted ordinary shares and restricted share units of the Company.

The computation of diluted loss per share for the six months ended June 30, 2022 and 2023 did not assume the exercise of share options, the vesting of unvested restricted share units and unvested restricted ordinary shares since their assumed exercise and vesting would be anti-dilutive.

8. DIVIDENDS

No dividend was paid, declared or proposed during the interim periods.

The directors of the Company have determined that no dividend will be paid in respect of the interim period.

9. RENTAL DEPOSITS/DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	At June 30, 2023 <i>RMB'000</i> (unaudited)	At December 31, 2022 <i>RMB'000</i> (audited)
Prepayments	24,094	19,589
Rental and other deposits	2,513	2,842
Value-added tax recoverable	49,171	46,172
Interests receivable	31,876	8,785
Other receivables	<u>2,061</u>	<u>2,765</u>
	<u>109,715</u>	<u>80,153</u>
Analysed as:		
Non-current	2,264	2,513
Current	<u>107,451</u>	<u>77,640</u>
	<u>109,715</u>	<u>80,153</u>

10. OTHER PAYABLES

	At June 30, 2023 <i>RMB'000</i> (unaudited)	At December 31, 2022 <i>RMB'000</i> (audited)
Payables for research and development expenses	24,919	113,531
Other payables for		
– legal and professional fee	7,187	2,225
– others	2,094	1,059
Other tax payables	1,307	1,861
Payroll payables	19,501	31,721
Accrued research and development expenses	19,304	3,397
Accrued issue costs	11,561	11,143
	<u>85,873</u>	<u>164,937</u>

Ageing analysis of the Group's payables for research and development expenses based on the invoice dates at the end of the reporting period is as follows:

	At June 30, 2023 <i>RMB'000</i> (unaudited)	At December 31, 2022 <i>RMB'000</i> (audited)
0-30 days	23,486	12,285
31-60 days	466	5,883
61-90 days	–	2,958
Over 90 days	967	92,405
	<u>24,919</u>	<u>113,531</u>

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

Since our inception, our mission has been to tackle major public health challenges with breakthrough scientific innovation driven by critical patient insight. Our senior executives' exceptional leadership skills and industry experience empower extensive execution across our broad therapeutic development strategy. Leveraging our unique business model, which combines internal discovery and strategic in-licensing, we are actively advancing our clinical programs. Our cross-border organic operations are one of our competitive advantages and position us for accelerated commercialization opportunities. With our presence in both China and U.S., we can utilize our respective strengths to accelerate the discovery, development and delivery of innovative medicines that have the potential to improve the health of patients around the world.

United in collaborative operations and a shared goal, our strategic program emphasis in China centers on our HBV functional curative therapy program as this is the area where we see opportunity to contribute significant and meaningful therapeutic impact for patients in the region and globally. The importance of our HBV assets was fortified by recent data presented by our partners Vir and VBI from multiple clinical studies for the treatment and prevention of chronic HBV infection at the EASL Congress 2023. The data presented further support the continued clinical evaluation of our assets, VIR-2218 (BR11-835) and (BR11-877), for which we in-licensed rights in Greater China, as a potential best-in-class functional cure for chronic HBV infection.

Looking at HBV prevention, despite national hepatitis B immunization programs for newborns in China and many other Asia Pacific countries, there remains an overlooked but persistent need for hepatitis B prophylactic vaccination among low coverage, high-risk adult populations. In these regions, there are over 200 million people ranging in age from 19 to 64 without anti-HBs protection, constituting a large HBV susceptible population. Meanwhile, portions of vaccinated individuals may fail to mount antibody levels and vaccine immunity may wane over time in patient populations with low level responses. There remains a heightened and unmet need to enhance vaccination in susceptible adults. The adoption of appropriate immunization strategies for susceptible adults will be an effective means to further prevent HBV infection and its consequences.

Leveraging our robust HBV assets and recent licensing, we are well-equipped to address HBV disease burdens from prevention to cure, positioning ourselves as a leading player in the pursuit of ending hepatitis B. Our pipeline of in-licensed HBV assets, including BR11-179 and PreHevbri[®], fortify our position. In July 2023, we extended our rights to include a global development and commercialization license for BR11-179 and we acquired the rights to develop and commercialize the novel HBV prophylactic vaccine PreHevbri[®] in Greater China and certain other Asia Pacific regions. PreHevbri[®] has already been approved for commercial use in multiple countries, supporting our near-term regulatory approval and commercialization efforts in China and other Asia Pacific regions.

In addition to HBV, we are actively advancing other promising programs. Our internally discovered CNS programs for the treatment of PPD/MDD are progressing well, with BR11-296 showing potential as a first-of-its-kind single-injection treatment option for PPD and MDD in the U.S. We are exploring expansion of indications for this candidate and have initiated a first-in-human Phase 1 trial with BR11-297 for anxiety and depressive disorders.

Furthermore, recognizing the widespread incidence of HIV around the world, we discovered and began developing a long-acting, once-weekly single tablet regimen for HIV patients with an initial focus in the U.S. We are seeking partnership opportunities for continued development of this long-acting treatment with our internally developed candidate BRII-732, as well as BRII-753, as a long-acting subcutaneous injection therapy with the goal to extend the dosing schedule to once monthly, once quarterly or once semi-annually.

For the MDR/XDR program, we are now solely focused on the development of BRII-693. The Company returned the exclusive rights of BRII-636 and BRII-672 in Greater China to Qpex, and received approximately US\$24 million upon closing of the acquisition as a Qpex shareholder and the return of the QPX7728 product rights, with potential contingency payments depending on future milestone events in the U.S. We now hold the exclusive global development and commercialization rights for BRII-693, and we have filed a pre-IND with the NMPA of China for its development in China. BRII-693 has demonstrated antibacterial mechanism and improved safety profile, making it a potential candidate for a safe and effective polymyxin for the treatment of critically ill patients with gram-negative bacterial infections.

In light of our strategic priorities for the second half of 2023, we are dedicated to:

- o Together with our partner Vir, further evaluating our combination treatment regimens under development for a higher functional cure rate for HBV infection leveraging the additional data available from several ongoing trials later this year, and planning to select a combination treatment regimen for the next stage of development in the Greater China;
- o Taking steps to commercialize PreHevbri® in China and other Asia Pacific regions;
- o Further advancing the clinical development of BRII-296 for the treatment of PPD/MDD, anxiety and other depressive disorders, as well as BRII-297 for the treatment of various anxiety and depressive disorders;
- o Exploring external strategic partnerships for our HIV program in the U.S. for continued development of our current product candidates as part of a long-acting treatment regimen for the treatment of HIV patients;
- o Expanding our pipeline through in-house discovery and additional licensing options. We are also exploring business development opportunities that expedite global regulatory approval by in-licensing therapies for use in China and out-licensing internally discovered therapeutic candidates for use in international markets; and
- o Continuing to optimize our organization in China and the U.S. to deliver innovation and expected performance to support our business development and establish a global patient-centric/people strategy built on our strong cultural foundation that lives through our mission to tackle the world's biggest challenges in public health.

Pipeline Summary

We have built a broad pipeline of more than 10 innovative drug candidates that focus on infectious diseases and central nervous system diseases. Our lead programs are HBV, primarily in China, along with PPD/MDD in the U.S. Furthermore, we maintain options to in-license two additional innovative HBV programs from our licensing partners.

Our strategic product pipeline is derived from (i) utilizing our in-house R&D capabilities to discover and develop our own innovative products and (ii) establishing collaborative licensing arrangements with carefully selected partners, whereby we in-license the Greater China/global rights to their important assets and lead the clinical development in China, playing an integral role in the global development of such assets. We have extended our global rights to BRII-179 as well as BRII-693. The following table sets forth the status of our key product candidates as of the date of this announcement:

Indication	Program	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Commercial	Our Rights	Partners
Infectious Disease Programs										
Hepatitis B	Treatment ⁽¹⁾									
	BRII-179 (VBI-2601)	[Progress bar: Phase 1 to Phase 2]							Global	VBI
	BRII-835 (VIR-2218)	[Progress bar: Phase 1 to Phase 2]							Greater China*	VIR
	BRII-877 (VIR-3434) ⁽²⁾	[Progress bar: Phase 1 to Phase 2]							Greater China*	VIR
	PreHevbri®	[Progress bar: Pre-clinical to Phase 2]							APAC ex-Japan ⁽³⁾	VBI
HIV	BRII-732	[Progress bar: Pre-clinical to Phase 1]							Global	Internally discovered
	BRII-753	[Progress bar: Pre-clinical]							Global	Internally discovered
MDR/XDR Gram-negative Bacterial Infections	BRII-693	[Progress bar: Pre-clinical to Phase 1]							Global	Monash University
NTM Lung Disease	BRII-658 (Epetraborole) ⁽⁴⁾	[Progress bar: Pre-clinical to Phase 2]							Greater China*	AN2Therapeutics
Central Nervous System Disease Programs										
PPD	BRII-296	[Progress bar: Pre-clinical to Phase 2]							Global	Internally discovered
Anxiety & Other Depressive Disorders	BRII-296	[Progress bar: Pre-clinical to Phase 1]							Global	Internally discovered
Anxiety & Depressive Disorders	BRII-297	[Progress bar: Pre-clinical to Phase 1]							Global	Internally discovered

*Greater China – Mainland China, Macau, Hong Kong and Taiwan
⁽¹⁾ The Phase 2 clinical trials conducted by Bri Bio
 • BRII-179 (VBI-2601) / PEG-IFN-α Combination study
 • BRII-179 (VBI-2601) / BRII-835 (VIR-2218) Combination study
 • BRII-835 (VIR-2218) ± PEG-IFN-α Combination study

⁽²⁾ The Phase 2 clinical trials have been conducted by Vir
⁽³⁾ PreHevbri® is currently approved for use in the United States, Canada, European Union, European Economic Area, the United Kingdom, and Israel. Bri Bio acquired exclusive rights for APAC countries (ex-Japan) in July 2023.
⁽⁴⁾ To this date, the development and clinical trials have been conducted by AN2.

BUSINESS REVIEW

During the Reporting Period, we rapidly advanced our product pipeline and business operations. Specifically, in addition to progressing clinical trials, we greatly enhanced our HBV portfolio. Based on increasingly compelling study data, we expanded our collaborations to include global development and commercialization rights for BR11-179. We also acquired commercialization rights in Greater China and Asia Pacific markets for PreHevbri[®], a clinically differentiated 3-antigen adult HBV prophylactic vaccine. These empower our HBV portfolio to address disease burdens from prevention to cure. In addition, we secured exclusive global rights for BR11-693 for the treatment of MDR/XDR gram-negative bacterial infections. Our primary achievements as of the date of this announcement along with our planned next steps and upcoming milestones include:

Our Drug Candidates

HBV Functional Cure Program (Licensed from VBI and Vir, China team core project)

As one of our leading clinical development programs, we are building a broad pipeline of novel HBV therapeutic candidates in order to improve the probability of achieving a high rate of functional cure for HBV patients. Each of our HBV candidates has a unique therapeutic modality with proven clinical benefit targeting this chronic infection, which allows the Company to explore an expansive set of potential combination treatment options for various patient subgroups. We hold exclusive global rights to develop and commercialize BR11-179 (VBI-2601), and exclusive rights in Greater China to develop and commercialize BR11-835 (VIR-2218) and BR11-877 (VIR-3434).

In July 2023, we expanded our HBV portfolio in collaboration with VBI. Under the terms of the agreements, we have extended our exclusive license to worldwide markets for BR11-179 (VBI-2601) and acquired exclusive rights to develop and commercialize PreHevbri[®] in Greater China and certain other Asia Pacific countries including Australia, Indonesia, Malaysia, New Zealand, Philippines, Singapore, South Korea, Thailand and Vietnam, among others.

BR11-179 (VBI-2601) in Combination with BR11-835 (VIR-2218) (Study conducted by Bii Bio)

BR11-179 (VBI-2601) is a novel recombinant protein-based HBV immunotherapeutic candidate that expresses the Pre-S1, Pre-S2 and S HBV surface antigens, and is designed to induce enhanced B-cell and T-cell immunity.

BR11-835 (VIR-2218) is a N-Acetylgalactosamine (GalNAc)-conjugated siRNA targeting all HBV viral RNAs that has shown to block viral transcription, reduce viral proteins and alleviate immune suppression.

Our BR11-179 (VBI-2601) and BR11-835 (VIR-2218) combination therapy may represent a novel HBV functional cure regimen. It encompasses dual mechanisms of action, removing immunosuppressive viral antigens by siRNA gene silencing followed by stimulating and restoring the host HBV specific immunity with an immunotherapeutic vaccine.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In February 2023, interim results were presented in an oral session at the APASL 2023 meeting indicating that combination therapy with BRII-835 (VIR-2218) and BRII-179 (VBI-2601) was safe and well-tolerated, induced stronger anti-HBsAg antibody responses and led to improved HBsAg-specific T-cell responses, when compared with BRII-835 (VIR-2218) or BRII-179 (VBI-2601) alone. The data presented at APASL showed that 50 participants in all cohorts achieved HBsAg reduction at the end of treatment with a mean decrease of -1.7 to -1.8 log₁₀ IU/mL. In addition, two participants in combination cohorts achieved maximum reductions in HBsAg at or below the lower limit of quantification by Week 40, along with robust HBsAg-specific antibody and T-cell responses.

Next Achievements and Upcoming Readouts

- Additional data from the Phase 2 study of BRII-179 (VBI-2601)/BRII-835 (VIR-2218) combination is expected in the second half of 2023.

BRII-179 (VBI-2601) in Combination with PEG-IFN- α (Study conducted by Bii Bio)

The study of BRII-179 (VBI-2601) and PEG-IFN- α combination therapy will assess BRII-179 (VBI-2601) as an add-on therapy to the standard-of-care, NRTI and PEG-IFN- α therapy, in non-cirrhotic chronic HBV patients.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In July 2023, we extended our license with VBI to include worldwide development and commercialization rights for BRII-179 (VBI-2601).
- In December 2022, we completed patient enrollment of approximately 120 patients in part one of a Phase 2 combination trial evaluating the addition of BRII-179 (VBI-2601) in chronic HBV patients already receiving PEG-IFN- α and NRTI treatment.

Next Achievements and Upcoming Readouts

- Topline results from the Phase 2 combination trial are expected in the second half of 2023.

VIR-2218 (BRII-835) in Combination with PEG-IFN- α

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In June 2023, Vir presented follow-up data at the European Association for the Study of the Liver Congress™ 2023 from its Phase 2 trial of combination 24 or 48 weeks of VIR-2218 (BRII-835) on top of a course of up to 48 weeks of PEG-IFN- α in which 16% (5/31) of participants demonstrated sustained HBsAg loss 24 weeks after end of treatment.
- Four participants with anti-HBs titers greater than 500 mIU/mL at the end of treatment achieved a sustained HBsAg loss at 24 weeks after the end of treatment suggesting the potential use of anti-HBs titers as an on-treatment biomarker of off-treatment sustained response.

- In August 2023, first patient has been dosed for an additional Phase 2 randomized and active-controlled study of BRII-835 (VIR-2218) in combination with PEG-IFN- α following regulatory approvals from multiple regulatory authorities in APAC including the NMPA of China.

Next Achievements and Upcoming Readouts

- We are actively working on the initiation of sites in APAC region for the study BRII-835 (VIR-2218) in combination with PEG-IFN- α .

VIR-2218 (BRII-835) in Combination with BRII-877 (VIR-3434) (MARCH Study conducted by Vir)

BRII-877 (VIR-3434) is an investigational subcutaneously administered HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes and to reduce the level of virions and subviral particles in the blood. BRII-877 (VIR-3434), which incorporates Xencor's Xtend™ and other Fc technologies, has been engineered to potentially function as a T cell vaccine against HBV in infected patients, as well as to have an extended half-life.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In June 2023, Vir presented clinical study results at the EASL Congress™ 2023. Data from Part A of Vir's Phase 2 MARCH trial evaluating short treatment duration of combinations of VIR-2218 (BRII-835) and VIR-3434 (BRII-877) in chronic HBV participants demonstrated a 2.7-3.1 log₁₀ IU/mL decline in HBsAg levels and 90% of participants achieved HBsAg reduction below 10 IU/mL at the end of treatment.
 - The majority of participants met the criteria for discontinuing NRTI therapy because they achieved all of the following: HBsAg less than 100 IU/mL and at or greater than 1 log₁₀ IU/mL reduction from baseline HBsAg level; HBV DNA below the LLOQ; HBeAg-negative and ALT at or less than twice the upper limit of normal. 67% (4/6) of those participants remained off NRTI therapy as of the last available follow up.
 - Combination treatment with VIR-2218 (BRII-835) and VIR-3434 (BRII-877) was generally well tolerated and associated primarily with mild adverse events. All treatment-related adverse events were Grade 1, with no study discontinuations.
- Vir also presented a poster at EASL Congress™ 2023 that highlighted the single dose pharmacokinetics of VIR-3434 (BRII-877) from a Phase 1 clinical trial in patients with chronic HBV infection, with data supporting continued evaluation of VIR-3434 (BRII-877).
 - The highest and most durable free VIR-3434 (BRII-877) exposure was observed with the 300 mg dose, regardless of baseline HBsAg level. Other doses evaluated include 6 mg, 18 mg and 75 mg.
 - VIR-3434 (BRII-877) has a shorter terminal half-life and was cleared faster in participants with higher baseline HBsAg.
- In August 2023, we received an IND approval from the CDE of NMPA of China for a Phase 1 study of BRII-877 (VIR-3434).

Next Achievements and Upcoming Readouts

- Initial data evaluating VIR-2218 (BRII-835) and VIR-3434 (BRII-877) with or without PEG-IFN- α are expected in the second half of 2023 from Part B of Vir's ongoing Phase 2 MARCH trial.
- A Phase 1 clinical study of BRII-877 (VIR-3434) conducted by Bii Bio is expected to start by the end of 2023.

PreHevbri®

PreHevbri® is a clinically differentiated and the only approved 3-antigen adult HBV prophylactic vaccine on the market. It is currently approved for adult use under the brand name PreHevbri® in the United States and Canada, under the brand name PreHevbri® in the European Union, European Economic Area, United Kingdom, and under the brand name Sci-B-Vac® in Israel. In pivotal Phase 3 clinical studies, PROTECT and CONSTANT, and subsequent investigator-initiated follow-up studies, PreHevbri® showed higher rates of and long-lasting seroprotection across all subjects aged 18 or above, and 5 to 8 times higher antibody titers, compared to Engerix-B, a single-antigen HBV vaccine. Moreover, an integrated safety analysis of both studies demonstrated that it is well tolerated with no unexpected reactogenicity observed.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In July 2023, Bii Bio entered into a definitive license agreement with VBI to acquire exclusive rights to develop and commercialize PreHevbri® in Greater China and certain other Asia Pacific countries including Australia, Indonesia, Malaysia, New Zealand, Philippines, Singapore, South Korea, Thailand and Vietnam, among others.
- In June 2023, VBI presented follow-up data in a subset of participants from the pivotal Phase 3 study, PROTECT, up to 3.5 years after completion of immunization with PreHevbri®, a prophylactic 3-antigen HBV vaccine to determine magnitude and duration of immune response. PreHevbri is a virus-like particle vaccine that consists of the same recombinant HBV surface antigens, Pre-S1, Pre-S2 and S, as are expressed in BRII-179 (VBI-2601).
 - At all measured timepoints, participants immunized with PreHevbri had significantly higher ($P < 0.0001$) mean HBsAg antibody titers as compared to those who were immunized with Engerix-B®.
 - The data highlight that PreHevbri induced T-cell responses against Pre-S1 and Pre-S2 proteins that correlated with high anti-HBs titers.
 - At 3.5 years follow up, the mean anti-HBs titers in participants vaccinated with PreHevbri were 5.1x higher than those vaccinated with Engerix-B (1,287 vs. 254 mIU/mL) suggesting that T-cell responses to PreHevbri may contribute to long lasting and strong humoral immune responses and greater durability compared with Engerix-B.

Next Achievements and Upcoming Readouts

- The Company is actively working towards the market launch of PreHevbri® in APAC markets, prioritizing regions or countries where additional trials may not be required. Market authorization application has been filed in Hong Kong.

Postpartum Depression and Major Depressive Disorders Program (Internally discovered, U.S. team core project)

Leveraging patient insights, we are developing BRII-296 and BRII-297 to expand treatment options for patients with psychiatric disorders who are often underserved and overlooked across the industry. Utilizing applied drug formulation know-how to develop long-acting therapies, we are focused on improving drug administration convenience and patient compliance to ensure potential treatment success.

BRII-296 is our novel, long-acting and single injection therapeutic candidate under development for the treatment of PPD/MDD. It acts as a gamma-aminobutyric acid A receptor positive allosteric modulator and is designed to provide a rapid, profound and sustained reduction in depressive symptoms of PPD/MDD with the potential to lead to greater adherence, convenience and fewer side effects compared to the current standard of care.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- Following an agreement with the U.S. FDA, we will start a Phase 2 POC study of BRII-296 in PPD investigating the first-of-its-kind, long acting, single treatment option in the third quarter of 2023.

Next Achievements and Upcoming Readouts

- We are actively working to expand the clinical indications for BRII-296 and plan to initiate additional studies in the U.S. in 2024.

BRII-297 is a new chemical entity discovered internally and under development as a long-acting injectable treatment of various anxiety and depressive disorders.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In June 2023, we announced that we had dosed the first subject in a first-in-human Phase 1 clinical trial in Australia for BRII-297. The study is underway and aims to evaluate the safety, tolerability and pharmacokinetics of BRII-297 in healthy volunteers.

HIV Program (Internally discovered)

The Company is seeking partnership opportunities to further develop its once-weekly, long-acting combination treatment of its oral single-tablet regimen of BRII-732, for the treatment of HIV. We are also seeking to develop partnership opportunities for a novel low volume, subcutaneous injection therapy, BRII-753, with potential to dose monthly, quarterly, or twice yearly as a combination treatment for HIV patients. Both compounds demonstrate considerable promise to serve as a key component for long-acting HIV treatment regimens that will offer more discreet and convenient options for patients living with HIV, and as monotherapy for Pre-Exposure Prophylaxis.

BRII-732 is a proprietary prodrug NCE that, upon oral administration, is rapidly metabolized into EFdA and is under evaluation as a potential HIV treatment or prevention option. BRII-732 is a NRTTI, acting as both a chain terminator and translocation inhibitor of HIV.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In the second quarter of 2023, Brie Bio initiated patient dosing in its Phase 1 study to investigate a lower oral dose of once-weekly BRII-732. This comes after the successful lifting of the U.S. FDA's previous clinical hold on clinical studies involving islatravir in December 2022.

Next Achievements and Upcoming Readouts

- We are exploring external partnership opportunities to continue developing BRII-732 as part of a potential oral, once-weekly, long-acting combination treatment option for HIV patients.

BRII-753 is a NCE currently in the preclinical stage of development. It has been internally discovered and is being developed as a long-acting injection for subcutaneous injection with potential for dosing monthly to every six months. BRII-753 can be used in a combination therapy for HIV treatment and as monotherapy for Pre-exposure Prophylaxis. The Company is currently pursuing partnership opportunities for further development of BRII-753.

MDR/XDR Gram-negative Bacteria Infections Program

BRII-693 (also previously known as QPX9003) is being developed under our global rights, which was secured in June 2023. The Company's acquisition of such global rights was associated with Qpex's acquisition by Shionogi and the Company's determination to prioritize and focus on the development of BRII-693 given its advanced microbiological and clinical profile.

BRII-693 has demonstrated antibacterial mechanism and improved safety profile, making it a potential candidate for a safe and effective polymyxin for the treatment of critically ill patients with gram-negative bacterial infections.

BRII-693 has obtained QIDP designation from the U.S. FDA, which provides incentives for the development of this agent in the U.S., including priority review and eligibility for the U.S. FDA's Fast Track Designation; there is also the potential for extension of regulatory and market exclusivity in the U.S.

BRII-693 is a novel synthetic lipopeptide in development for the treatment of MDR/XDR gram-negative bacterial infections. Based on a combination of increased in vitro and in vivo potency, and an improved safety profile compared with currently available polymyxins, BRII-693 has the potential to be an important addition to the arsenal of hospital-administered intravenous antibiotics. BRII-693 has a highly differentiated safety and efficacy profile to address the most difficult-to-treat infections due to *Acinetobacter baumannii* and *Pseudomonas aeruginosa*, including infections due to MDR/XDR isolates resistant to carbapenem antibiotics.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- In June 2023, we expanded our existing rights to develop and commercialize BRII-693 in Greater China to exclusive global rights.
- In April 2023, we submitted a pre-IND to the NMPA of China for the development of BRII-693 in China.

Next Achievements and Upcoming Readouts

- We are actively working on the future global development plan of BRII-693 and the IND application in China is also on track.

NTM Lung Disease Program (Licensed from AN2)

Brii Bio's strategic partner, AN2, is developing epetraborole (BRII-658) as a once-daily oral treatment for patients with chronic NTM lung disease, with an initial focus on treatment-refractory *Mycobacterium avium complex* lung disease. It is a boron-containing, small molecule inhibitor of mycobacterial leucyl-tRNA synthetase, or LeuRS, an enzyme involved in protein synthesis. We hold a license to develop, manufacture, and commercialize epetraborole (BRII-658) in the Greater China.

Clinical Development Milestones and Achievements as at the Date of This Announcement

- Our partner, AN2, is currently enrolling patients in its Phase 2/3 pivotal trial evaluating once-daily, oral epetraborole for treatment-refractory MAC lung disease at over 90 sites across the U.S. Japan, South Korea and Australia.
- AN2 expects to complete enrollment in the Phase 2 portion of the Phase 2/3 pivotal trial and begin Phase 3 portion in September 2023 and to announce top-line data from the Phase 2 portion of the study in summer 2024.

Other Corporate Developments

- In July 2023, Dr. David Margolis was appointed as Chief Medical Officer, replacing Dr. Li Yan who departed from the Company to pursue other interests. Dr. Margolis has served as Brie Bio's Head of Infectious Diseases Therapy Area for nearly three years and will continue to fulfill his existing responsibilities in addition to his new role as Chief Medical Officer.
- We continued to foster partnerships with key maternal health advocacy groups to address patients' needs and preferences in the U.S., including sponsoring the 2023 Maternal Mental Health Forum, the 5th annual Black Maternal Mental Health Week, the 2023 Climb Out of the Darkness event, and the Mind the Gap strategic action plan by Postpartum Support International at the 36th Annual PSI Conference.
- In April 2023, Brie Bio published its 2022 Environmental, Social and Governance Report, outlining the Company's progress and performance towards long-term growth and success in key ESG areas. We have also been awarded an "A" rating from MSCI ESG Rating, a globally recognized assessment of a company's resilience to long-term ESG risks.

Research & Development

We are a biotech company primarily engaged in pharmaceutical R&D activities. We believe that R&D is fundamental to shaping our therapeutic strategy and maintaining our competitiveness in the biopharmaceutical industry.

Patients' needs play an integral role in determining which diseases we target. Currently, our portfolio aims to find more viable solutions to prevalent diseases that impact a growing number of people with infectious diseases and mental illnesses. We intentionally target diseases where we have clear insights into patients' needs or preferences.

Our teams are geographically delineated by disease indication with different emphases in the U.S. and China to better leverage our capabilities and create additional competitive advantages. In the U.S., we are developing our CNS and HIV programs, as well as leveraging our partners' clinical data to move through clinical development more swiftly in China, or participate in late-stage global studies, where our focal programs are HBV and MDR/XDR. The rapid approval and commercialization of our COVID-19 neutralizing antibodies combination is an excellent example of how our international teams work together. While our U.S. and China teams currently have separate therapeutic areas of focus, we are united in our operations and our shared vision to deliver world-class medicines to patients.

Our R&D collaborations and in-house R&D capabilities facilitate our global sourcing of innovative therapies for China and global markets. We have built our drug candidates by leveraging our in-house R&D capabilities, collaborations and support from our strong scientific advisory board and veteran investors. Additionally, we have R&D collaborations with global pharmaceutical and biotech companies, leading CROs, CMOs, CDMOs, research institutions and other strategic partners. Our cross-border organic operations are one of our competitive advantages and we plan to extend this capability and our capacity to our organization. With the planned expansion of our depressive disorders pipeline, we may consider establishing additional laboratories that serve our international goals, such as advancing our U.S. capabilities.

Our in-house R&D capabilities are led by industry veterans who impart the Company with their large pharma experience in drug discovery all the way through commercialization. Our leaders include Chief Executive Officer Dr. Zhi Hong; Chief Medical Officer Dr. David Margolis; Head of China R&D Dr. Qing Zhu; CNS Diseases Therapy Area Head Dr. Aleksandar Skuban; and Head of Discovery Dr. Ji Ma.

With widely respected members in our Board who are well regarded in the industry, our R&D process and drug candidate selection are guided by a leading team of experts. Our diverse Board members hold exceptional industry experience across multiple scientific and corporate disciplines, including leadership at large biopharmaceutical companies, specialization in infectious diseases, and track record of successfully bringing biologic candidates through the clinical development, regulatory review and commercialization process.

By design, our multi-pronged R&D strategies entail R&D expenses that vary with the number and scale of projects each year. Our R&D expenses were RMB202.2 million for the six months ended June 30, 2023. We intend to continue to leverage our technology and R&D capabilities to broaden our life sciences research and application capabilities and product candidate portfolio.

Commercialization

In July 2023, the Company acquired exclusive rights to develop and commercialize PreHevbri® in Greater China and certain other Asia Pacific regions. Since then, we have initiated pathway mapping and have been collaborating with local regulatory authorities to expedite the market launch of PreHevbri®. Our focus is on prioritizing regions where additional trials may not be required and where we see near-term revenue opportunities. The market authorization application in Hong Kong has already been filed and we are also exploring fast-track approvals in other APAC regions.

For our pipeline drug candidates, we maintain a mix of in-licensed Greater China rights and global rights.

Most of our programs are in different stages of clinical development and we do not anticipate sales or commercialization of other drug candidates in the immediate future.

As at the date of this announcement, our efforts have primarily focused on building our drug candidate pipeline.

As our pipeline matures, we will further evaluate strategic commercialization for our various drug candidates.

FUTURE DEVELOPMENT

Our mission is to develop and bring transformative therapies to underserved markets, address critical public health needs and become a leader in infectious diseases and central nervous system disease solutions.

Our focus is wholly dedicated to our core development programs in HBV, primarily in China, where we are an industry frontrunner, as well as our psychiatric disorders programs, where we are accelerating our clinical development in depressive disorders treatment in the U.S.

Our strategic priorities for the second half of 2023 are to:

- o Together with our partner Vir, further evaluating our combination treatment regimens under development for a higher functional cure rate for HBV infection leveraging the additional data available from several ongoing trials later this year, and plan to select a combination treatment regimen for the next stage of development in the Greater China;
- o Take steps to commercialize PreHevbri® in China and other Asia Pacific regions;
- o Continue to advance the clinical development of BRII-296 for the treatment of PPD/MDD, anxiety and other depressive disorders, as well as to advance BRII-297 for the treatment of various anxiety and depressive disorders;
- o Explore strategic partnership for our HIV program in the U.S. for continued development of our current product candidates as a long-acting treatment regimen for the treatment of HIV patients;
- o Expand our pipeline through in-house discovery and additional licensing options. Explore business development opportunities that expedite global regulatory approval by in-licensing therapies for use in China and out-licensing internally discovered therapeutic candidates for use in international markets; and
- o Continue to optimize our organization in China and the U.S. to deliver innovation and expected performance to support our business development and establish a global patient-centric/people strategy built on our strong cultural foundation that lives through our mission to tackle the world's biggest challenges in public health.

Subsequent Events

Business Update related to Licensing Agreements

In July 2023, Brie Bio entered into license agreements with VBI, expanding the Company's collaboration in the HBV field. The newly formed license agreements with VBI signify a substantial expansion in the fight against hepatitis B infection and empower Brie Bio's robust HBV portfolio to address disease burdens from prevention to cure.

Brie Bio's exclusive license for BRII-179 (VBI-2601) is extended to worldwide markets, further establishing its leadership position in pursuing HBV functional cure. A growing body of evidence supports the importance of a strong HBV-specific immune response to achieve a durable HBV functional cure, highlighting a potentially important role for BRII-179 as part of a combination cure strategy.

Additionally, Brie Bio acquired exclusive rights to develop and commercialize PreHevbri® in Greater China and certain other Asia Pacific countries including Australia, Indonesia, Malaysia, New Zealand, Philippines, Singapore, South Korea, Thailand and Vietnam, among others. PreHevbri® is a clinically differentiated 3-antigen adult HBV prophylactic vaccine recently approved for use in the United States, European Union/European Economic Area, United Kingdom, Canada and Israel. Under the terms of the agreements, VBI has received upfront payments of an aggregate of US\$15 million from Brie Bio, including US\$5 million ring-fence for manufacturing and supply of BRII-179 (VBI-2601) or PreHevbri® as well as US\$3 million equity investment in VBI by Brie Bio. VBI is also entitled to an upfront license fee of US\$7 million for BRII-179 (VBI-2601) and PreHevbri® and is eligible to receive additional payments based on achievement of certain milestones, as well as royalties.

FINANCIAL REVIEW

1. Revenue

The revenue increased by RMB0.6 million from nil for the six months ended June 30, 2023. The increase was attributable to the commercialization of the long-acting amubarvimab/romlusevimab combination therapy in China for the treatment of COVID-19. Revenue is recognised when control of the goods has been transferred, being when the goods have been delivered to the specified location designated by the customers.

2. Other income

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Government grants	39,480	27,885
Bank interest income	46,383	10,343
	<hr/>	<hr/>
Total	85,863	38,228
	<hr/> <hr/>	<hr/> <hr/>

Our other income increased by RMB47.7 million from RMB38.2 million for the six months ended June 30, 2022 to RMB85.9 million for the six months ended June 30, 2023. The increase was primarily due to the increased bank interest income of RMB36.1 million attributable to the additional placement of time deposits with original maturity over three months. The increase was also due to the increase in the recognition of government grants income of RMB11.6 million. These grants mainly represent the incentive and other subsidies from the PRC government, which are for research and development activities, and are recognized upon compliance with the attached conditions.

3. Other gains and losses

Our other gains and losses increased by RMB57.3 million from losses of RMB34.0 million for the six months ended June 30, 2022 to gains of RMB23.3 million for the six months ended June 30, 2023. The increase was primarily attributable to the fair value gain on financial assets and the differences resulting from the foreign currency exchange rates on the carrying amount of financial assets denominated in a foreign currency.

4. Fair value loss on equity instruments at FVTOCI

Our fair value loss on equity instruments at FVTOCI decreased by RMB18.3 million from loss of RMB22.8 million for the six months ended June 30, 2022 to loss of RMB4.5 million for the six months ended June 30, 2023. The amount represents the equity investment in a biopharmaceutical company listed in the USA. The fair value of the listed equity investment is measured based on quoted market price.

5. Research and development expenses

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Third-party contracting cost	108,720	168,357
Employee cost	89,295	80,223
Licensing fees	–	6,487
Amortization	1,358	1,358
Others	2,802	2,059
Total	<u>202,175</u>	<u>258,484</u>

Our research and development expenses decreased by RMB56.3 million from RMB258.5 million for the six months ended June 30, 2022 to RMB202.2 million for the six months ended June 30, 2023. The decrease was primarily attributable to the decrease in third-party contracting cost of RMB59.7 million. The decrease was partially offset by the employee cost increased by RMB9.1 million due to the increase in research and development headcounts for our continuous development in clinical during the period.

6. Administrative expenses

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Employee cost	65,016	63,222
Professional fees	16,133	15,751
Depreciation and amortization	7,158	6,956
Office expenses	2,438	2,088
Others	12,078	7,450
Total	<u>102,823</u>	<u>95,467</u>

Our administrative expenses increased by RMB7.3 million from RMB95.5 million for the six months ended June 30, 2022 to RMB102.8 million for the six months ended June 30, 2023. This was primarily attributable to an increase of RMB4.6 million in other expenses mainly due to the increased computer software fees. In addition, employee cost increased by RMB1.8 million from RMB63.2 million for the six months ended June 30, 2022 to RMB65.0 million for the six months ended June 30, 2023, which was primarily attributable to the increase in employee headcounts.

7. Liquidity and Capital resources

As of June 30, 2023, our bank and cash balances, including restricted bank deposits and time deposits, decreased to RMB2,740.9 million from RMB2,999.3 million as of December 31, 2022. The decrease is primarily due to payout of daily operations and third-party contracting cost.

8. Non-IFRS measures

To supplement the Group's consolidated financial statements, which are presented in accordance with the IFRS, we also use adjusted loss for the period and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, the IFRS. We believe that these adjusted measures provide useful information to Shareholders and potential investors in understanding and evaluating our consolidated results of operations in the same manner as they help our management.

Adjusted loss for the period represents the loss for the period excluding the effect of certain non-cash items and one-time events, namely share-based compensation expenses. The term adjusted loss for the period is not defined under the IFRS. The use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute for analysis of, our results of operations or financial condition as reported under IFRS. The presentation of such adjusted figures may not be comparable to a similarly titled measure presented by other companies. However, we believe that this and other non-IFRS measures are reflections of our normal operating results by eliminating potential impacts of items that the management does not consider to be indicative of our operating performance, and thus facilitate comparisons of operating performance from period-to-period and company-to-company to the extent applicable.

The table below sets forth a reconciliation of the loss to adjusted loss during the periods indicated:

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Loss for the period	(196,826)	(365,614)
Added:		
Share-based compensation	33,126	53,988
Adjusted loss for the period	<u>(163,700)</u>	<u>(311,626)</u>

The table below sets forth a reconciliation of the research and development expenses to adjusted research and development expenses during the periods indicated:

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Research and development expenses for the period	(202,175)	(258,484)
Added:		
Share-based compensation	<u>16,324</u>	<u>22,082</u>
Adjusted research and development expenses for the period	<u>(185,851)</u>	<u>(236,402)</u>

The table below sets forth a reconciliation of the administrative expenses to adjusted administrative expenses during the periods indicated:

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Administrative expenses for the period	(102,823)	(95,467)
Added:		
Share-based compensation	<u>19,356</u>	<u>25,901</u>
Adjusted administrative expenses for the period	<u>(83,467)</u>	<u>(69,566)</u>

9. Key financial ratios

The following table sets forth the key financial ratios for the dates indicated:

	As at June 30, 2023	As at December 31, 2022
Current ratio ⁽¹⁾	2,553%	1,343%
Gearing ratio ⁽²⁾	NM	NM

(1) Current ratio is calculated using current assets divided by current liabilities as of the same date. Current ratio increased mainly due to the decrease in other payables as we have paid out most of the payables for third-party contracting cost.

(2) Gearing ratio is calculated using interest-bearing borrowings less cash and cash equivalents divided by (deficiency of) total equity and multiplied by 100%. Gearing ratio is not meaningful as we do not have any interest-bearing borrowings.

10. Indebtedness

Borrowings

As at June 30, 2023, the Group did not have any unutilized bank facilities, material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, hire purchase commitments, liabilities under acceptances (other than normal trade bills) or acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured.

Contingent Liabilities

As at June 30, 2023, the Group did not have any contingent liabilities.

Lease liabilities

We lease our office places under operating lease arrangements. Leases for office places are negotiated for terms ranging mainly from one to five years. As at June 30, 2023, the Group had lease liabilities of RMB8.0 million recognized under IFRS 16.

11. Significant investments, material acquisitions and disposals

As at June 30, 2023, we did not hold any significant investments. For the six months ended June 30, 2023, we did not have material acquisitions or disposals of subsidiaries, associates, and joint ventures.

12. Charge on the Group's assets

As at June 30, 2023, none of the Group's assets were charged with any parties or financial institutions (December 31, 2022: nil).

13. Foreign exchange exposure

We are exposed to foreign exchange risk arising from certain currency exposures. Our reporting currency is RMB, but a significant portion of our operating transactions, assets, and liabilities are denominated in other currencies such as USD and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

As at June 30, 2023, the Group's restricted bank deposits, time deposits with original maturity over three months and cash and cash equivalents were denominated as to 40.6% in US dollars, 40.4% in Hong Kong dollars, and 19.0% in RMB.

14. Employees and remuneration

As at June 30, 2023, we had a total of 133 employees. The following table sets forth the total number of employees by function as of June 30, 2023:

Function	Number of employees	% of total
Research and development	92	69%
Administration	41	31%
Total	<u>133</u>	<u>100%</u>

We enter into individual employment contracts with our employees to cover matters such as wages, benefits, equity incentive, and grounds for termination. We generally formulate our employees' remuneration package to include salary, bonus, equity incentive and allowance elements. Our compensation programs are designed to remunerate our employees based on their performance, measured against specified objective criteria. We also provide our employees with welfare benefits in accordance with applicable regulations and our internal policies.

The Group also has adopted share incentive schemes for the purpose of providing incentives and rewards to its employees.

In accordance with applicable regulations in the PRC, we participate in a pension contribution plan, a medical insurance plan, an unemployment insurance plan, and a personal injury insurance plan for our employees. We have made adequate provisions in accordance with applicable regulations. Additionally, in accordance with PRC regulations, we make annual contributions toward a housing fund, a supplemental medical insurance fund, and a maternity fund.

We provide formal and comprehensive company-level and department-level training to our new employees followed by on-the-job training. We also provide training and development programs to our employees from time to time to ensure their awareness and compliance with our various policies and procedures. Some of the training is conducted jointly by different groups and departments serving different functions but working with or supporting each other in our day-to-day operations.

The total remuneration cost incurred by the Group for the six months ended June 30, 2023 was RMB155.0 million, as compared to RMB157.4 million for the six months ended June 30, 2022.

15. Treasury policy

Majority of our cash arises from equity funding. Such cash can only be invested in relatively liquid and low-risk instruments such as bank deposits or money market instruments. The primary objective of our investments is to generate finance income at a yield higher than the interest rate of current bank deposits, with an emphasis on preserving principal and maintaining liquidity.

OTHER INFORMATION

USE OF PROCEEDS FROM THE GLOBAL OFFERING

On July 13, 2021, the Company was successfully listed on the Stock Exchange. The net proceeds received by the Group from the Global Offering (including the partial exercise of the over-allotment option) amounted to approximately HK\$2.614 billion (after deducting underwriting fee and relevant expenses).

Details of the planned applications of the net proceeds from the Global Offering were disclosed in the Prospectus and subsequently revised and disclosed in the annual results announcement of the Company dated March 24, 2023. The table below sets out the planned applications of the net proceeds and the actual usage up to June 30, 2023:

Use of proceeds	Percentage of total net proceeds	Allocation of net proceeds (HK\$ million)	Unutilized amount as at December 31, 2022 (HK\$ million)	Utilized amount during the Reporting Period (HK\$ million)	Utilized amount up to June 30, 2023 (HK\$ million)	Unutilized amount as at June 30, 2023 (HK\$ million)
Used for our HBV functional cure programs	38%	994.1	686.8	67.9	375.2	618.9
To fund ongoing and planned clinical trials and preparation for regulatory filings for developing combination regimens containing BRII-179, BRII-835 or BRII-877	32%	837.3	530.0	67.9	375.2	462.1
Used for regulatory milestone payments for BRII-179	1%	26.1	26.1	–	–	26.1
Used for the launch and commercialization of HBV curative treatment regimens	5%	130.7	130.7	–	–	130.7
Used for our HIV programs, funding the ongoing and planned non-clinical studies, clinical trials and preparation for registration filings for BRII-732 and BRII-753	7%	176.0	70.7	15.9	121.2	54.8
Used for our MDR/XDR gram-negative infections programs	11%	294.0	259.9	9.6	43.7	250.3
To fund the ongoing and planned clinical trials and preparation for registration filings for BRII-636, BRII-672 and BRII-693	9%	234.5	208.9	9.6	35.2	199.3
Used for regulatory milestone payments for BRII-636, BRII-672 and BRII-693	2%	59.5	51.0	0.0	8.5	51.0
Used for our CNS programs, funding the ongoing and planned non-clinical studies, clinical trials and preparation for registration filings for BRII-296, BRII-297 and other pre-clinical/clinical candidates	19%	496.3	380.3	61.4	177.4	318.9
Used for discovery and business development activities for pipeline expansion	15%	392.0	334.8	8.3	65.5	326.5
Used for working capital and general corporate purposes	10%	261.4	57.2	57.2	261.4	0.0
Total	100%	2,613.8	1,789.7	220.3	1,044.4	1,569.4

For the Company's planned usage of the proceeds as described above, the Company expects that the net proceeds will be used up by the end of 2025.

The unutilized net proceeds will be applied in a manner consistent with the above planned applications and remains subject to change based on our current and future development of market conditions and actual business needs.

INTERIM DIVIDEND

The Board did not declare an interim dividend for the six months ended June 30, 2023.

CORPORATE GOVERNANCE PRACTICES

The Group is committed to maintaining high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability.

The Company has adopted the principles and the code provisions contained in the CG Code as set out in Appendix 14 to the Listing Rules as its own code of corporate governance. During the Reporting Period, the Company has complied with all applicable code provisions of the CG Code save and except for the following deviation from code provision C.2.1 of the CG Code.

Under code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Accordingly, the appointment of Dr. Zhi Hong ("**Dr. Hong**") as the chairman of the Board and the chief executive officer of the Company deviates from the relevant code provision. Dr. Hong, as the founder of the Group, has extensive experience in the biopharmaceutical industry and has served in the Company since its establishment. Dr. Hong is in charge of overall management, business, strategic development and scientific research and development of the Group. The Board considers that vesting the roles of the chairman of the Board and the chief executive officer of the Company in the same person, Dr. Hong, is beneficial to the management of the Group. The Board also believes that the combined role of the chairman of the Board and the chief executive officer of the Company can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board.

The balance of authority and control is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises two executive Directors, one non-executive Director and five independent non-executive Directors, and therefore has a strong independent element in its composition. The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairman and the chief executive officer is necessary.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted its own code of conduct regarding securities transactions of the Directors (the "**Company's Code**") on terms no less exacting than the required standard set out in the Model Code as set out in Appendix 10 to the Listing Rules. Having made specific enquiry with the Directors, all Directors confirmed that they have complied with the required standard as set out in the Model Code and the Company's Code during the Reporting Period. No incident of non-compliance of the Model Code or the Company's Code by the relevant employees who are likely to be in possession of unpublished inside information of the Company was noted by the Company.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

During the Reporting Period, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's listed securities.

REVIEW OF INTERIM RESULTS

The external auditors of the Company, namely Deloitte Touche Tohmatsu, have carried out a review of the unaudited condensed consolidated financial statements of the Group for the six months ended June 30, 2023 in accordance with the Hong Kong Standard on Review Engagement 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants.

The Board has established the Audit and Risk Committee which comprises three independent non-executive Directors, namely Ms. Grace Hui Tang, Dr. Taiyin Yang and Mr. Yiu Wa Alec Tsui. Ms. Grace Hui Tang and Dr. Taiyin Yang serve as the co-chairladies of the Audit and Risk Committee, who have the professional qualification and experience in financial matters in compliance with the requirements of the Listing Rules. The primary duties of the Audit and Risk Committee are to review and supervise the Company's financial reporting process, risk management and internal control system.

The Audit and Risk Committee, together with the management and external auditor of the Company, has reviewed the accounting principles and policies adopted by the Company and discussed the risk management and internal control system and financial reporting matters of the Group (including the review of the unaudited condensed consolidated financial statements of the Group for the six months ended June 30, 2023) and is of the view that the interim results of the Group for the six months ended June 30, 2023 is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

PUBLICATION OF THIS INTERIM RESULTS ANNOUNCEMENT AND THE INTERIM REPORT

This interim results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.briibio.com). The interim report of the Company for the six months ended June 30, 2023 containing all the information required by the Listing Rules will be despatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions shall have the following meanings.

“AIDS”	acquired immunodeficiency syndrome, defined as an HIV infection with either a CD4+ T-cell count below 200 cells per μL or the occurrence of specific diseases associated with HIV infection
“ALT”	alanine transaminase
“AN2”	AN2 Therapeutics, Inc., a corporation incorporated in Delaware, U.S., whose stocks are listed on the NASDAQ Global Select Market (NASDAQ: ANTX)
“anti-HBs”	Hepatitis B surface antibody
“APAC”	Asia Pacific
“APASL”	the Asian Pacific Association for the Study of the Liver
“ART”	antiretroviral therapy
“Audit and Risk Committee”	the audit and risk committee of the Board
“Board”	the board of directors of the Company
“CD4”	cluster of differentiation antigen 4
“CDE”	the Center for Drug Evaluation
“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“CG Code”	the Corporate Governance Code contained in Appendix 14 to the Listing Rules
“China” or “the PRC”	the People’s Republic of China excluding, for the purposes of this announcement, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“CMO”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide drug manufacturing services

“CNS”	central nervous system, part of the nervous system consisting of the brain and spinal cord
“Company”, “we”, “us” or “Brii Bio”	Brii Biosciences Limited (騰盛博药生物科技有限公司), an exempted company with limited liability incorporated under the laws of the Cayman Islands, the Shares of which are listed on the Main Board of the Stock Exchange
“COVID-19”	Coronavirus Disease 2019, a disease caused by the novel virus 2 SARS-CoV-2 and designated as severe acute respiratory syndrome
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“Director(s)”	director(s) of the Company
“DNA”	deoxyribonucleic acid
“EASL”	European Association for the Study of the Liver
“EFdA” or “islatravir”	an NRTTI and an investigational drug for the treatment of HIV infection
“ESG”	environmental, social and governance
“GABA _A ”	γ -aminobutyric acid sub-type A receptors
“Global Offering”	the Hong Kong initial public offering and the international offering of the Company
“Greater China”	Mainland China, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“Group”	the Company and its subsidiaries
“HBeAg”	hepatitis B e antigen
“HBsAg”	hepatitis B surface antigen
“HBV”	hepatitis B virus
“HIV”	human immunodeficiency virus
“Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic of China
“Hong Kong dollars” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or clinical trial notification in Australia
“IT”	information technology
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange
“LLOQ”	lower limit of quantification
“MAC”	mycobacterium avium complex, an infection caused by two types of bacteria
“MARCH”	Monoclonal Antibody siRNA Combination against Hepatitis B
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuer as set out in Appendix 10 to the Listing Rules
“MDD”	major depressive disorders
“MDR/XDR”	multi-drug resistant/extensive drug resistant
“MSCI”	MSCI Inc., an American finance company
“NCE”	new chemical entity
“NMPA”	the National Medical Products Administration
“NRTI”	nucleotide/nucleoside reverse transcriptase inhibitors, a form of ART used to treat HIV infection or AIDS
“NTM”	nontuberculous mycobacteria
“PAM”	positive allosteric modulators
“PEG-IFN- α ”	pegylated interferon alfa
“POC”	proof of concept
“PPD”	postpartum depression
“Prospectus”	the prospectus of the Company dated June 30, 2021
“PSI”	Postpartum Support International
“QIDP”	Qualified Infectious Disease Product
“Qpex”	Qpex Biopharma Inc., a corporation incorporated in Delaware, United States
“Reporting Period”	the six months ended June 30, 2023

“RMB”	Renminbi, the lawful currency of the PRC
“RNA”	ribonucleic acid
“R&D”	research and development
“SARS-CoV-2”	severe acute respiratory syndrome coronavirus 2
“Share(s)”	ordinary share(s) in the share capital of the Company with a nominal value of US\$0.00001 each
“Shareholder(s)”	the holder(s) of the Share(s)
“siRNA”	small interfering RNA, sometimes known as short interfering RNA or silencing RNA, a class of double stranded non-coding RNA molecules
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States” or “U.S.” or “USA”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. FDA”	the U.S. Food and Drug Administration
“VBI”	VBI Vaccines Inc., a corporation with corporate headquarters in Cambridge, the United States, whose stocks are listed on the NASDAQ Global Market (NASDAQ: VBIV)
“Vir”	Vir Biotechnology, Inc., a corporation incorporated in San Francisco, the United States, whose stocks are listed on the NASDAQ Global Market (NASDAQ: VIR)
“%”	per cent.

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

Hong Kong, August 22, 2023

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.