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Breakthrough innovation & insight

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)

# ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2024 AND CHANGE IN USE OF PROCEEDS

The Board is pleased to announce the consolidated annual results of the Group for the year ended December 31, 2024, together with the comparative figures for the previous year, which have been reviewed by the Audit and Risk Committee.

# FINANCIAL HIGHLIGHTS

- Our bank deposits and cash and cash equivalents were RMB2,413.4 million as of December 31, 2024, representing a decrease of RMB248.0 million or 9.3% compared with RMB2,661.4 million as of December 31, 2023. The decrease was primarily due to payout of daily operations and research and development activities.
- Other income was RMB141.4 million for the year ended December 31, 2024, representing a decrease of RMB22.3 million or 13.6%, compared with RMB163.7 million for the year ended December 31, 2023. This was mainly due to the decrease in bank interest income of RMB20.8 million attributable to the declining interest rates on USD and HKD time deposits and the decrease in income recognized from PRC government grants.
- Research and development expenses were RMB249.8 million for the year ended December 31, 2024, representing a decrease of RMB152.9 million or 38.0%, compared with RMB402.7 million for the year ended December 31, 2023. The decrease was primarily attributable to the decrease in third-party contracting cost of RMB79.3 million and the decrease in employee cost of RMB67.7 million, which were primarily due to pipeline prioritization and organizational optimization during the Reporting Period.
- Administrative expenses were RMB153.2 million for the year ended December 31, 2024, representing a decrease of RMB43.3 million or 22.0%, compared with RMB196.5 million for the year ended December 31, 2023. The decrease was primarily attributable to the decrease in employee cost of RMB39.7 million, which was primarily attributable to pipeline prioritization and organizational optimization during the Reporting Period.
- Loss for the year was RMB512.4 million for the year ended December 31, 2024, representing an increase of RMB328.0 million or 177.9%, compared with RMB184.4 million for the year ended December 31, 2023. The increase in loss was primarily attributable to investment-related losses of RMB126.1 million and impairment losses of RMB90.3 million, partially offset by the decrease in research and development expenses and administrative expenses. In contrast to the prior year, which benefited from a significant gain on the one-time sale of assets of RMB131.8 million and the increase in the share price of an equity investment of RMB129.2 million, the current year was impacted by a decline in the fair value of the same equity investment.

# **BUSINESS HIGHLIGHTS**

During the Reporting Period, Brii Bio advanced its pipeline with a primary focus on its leading hepatitis B virus functional cure program. Throughout 2024, Brii Bio made significant progress towards its goal of achieving a higher functional cure rate for patients with chronic hepatitis B, gaining valuable data from ongoing Phase 2 trials.

Bri Bio's clinical strategy focuses on identifying the most effective curative regimens for different HBV population subsets while pursuing the most efficient regulatory path to approval. This approach involves multiple ongoing Phase 2 clinical studies, namely the ENSURE study, the ENRICH study, and the ENHANCE study. These studies test different HBV combination treatment regimens, including BRII-179, a recombinant protein-based HBV immunotherapeutic; elebsiran, an HBV-targeting siRNA; and tobevibart, a broadly neutralizing monoclonal antibody targeting HBV surface antigen. Each of these assets offers a distinct therapeutic perspective. Among them, Brii Bio believes BRII-179 is a key differentiator through stimulating and restoring HBV-specific immune response for cure.

In November 2024, Brii Bio presented the end-of-treatment data from cohorts 1-3 of its ENSURE study that suggested a direct role of elebsiran in achieving a higher HBV functional cure rate. Elebsiran is currently being evaluated in multiple ongoing clinical trials with BRII-179, sponsored by Brii Bio, and tobevibart, sponsored by Vir Biotechnology. In December 2024, Brii Bio completed enrollment in its ENRICH study to evaluate the role of BRII-179 in priming HBV-specific immunity as part of a curative regimen and as a tool to identify immuno-responsive patients with a higher probability of achieving a functional cure. Further datasets from the ongoing ENRICH and ENSURE studies are expected throughout 2025 and 2026 and will guide Brii Bio's late-stage development and registration strategy.

In December 2024, Brii Bio acquired full intellectual property rights and related assets for BRII-179 from VBI and its subsidiaries, enhancing the potential commercial value of this asset by eliminating future royalty obligations and ensuring uninterrupted clinical supply of BRII-179 for its ongoing and future studies.

In recognition of Brii Bio's innovative candidates for HBV cure, elebsiran, tobevibart and BRII-179 have all been granted Breakthrough Therapy Designation by the CDE. Vir Biotechnology was also granted Fast Track designations for elebsiran and tobevibart for the treatment of chronic hepatitis D in June 2024 by the U.S. FDA. This was followed by Orphan designation granted to Vir Biotechnology by the EMA in November 2024. In December 2024, Vir Biotechnology received Breakthrough Therapy Designation from the U.S. FDA and Prime designation from the EMA.

With a strong focus on its HBV functional cure programs, the development of other clinical programs of Brii Bio including its therapeutic candidates for HIV and MDR/XDR infections is contingent on external partnerships. In October 2024, Brii Bio received IND approval from the CDE for a Phase 1 PK bridging study in China with its MDR/XDR infections program BRII-693.

Brii Bio also strengthened its discovery pipeline across new targets and platform technologies with expansion of its early discovery team and the appointment of a Chief Scientific Officer in 2024. This strategic investment reinforces Brii Bio's commitment to advancing research and delivering cutting-edge solutions for patients worldwide.

For further details, please refer to the rest of this announcement, as well as the Company's prior announcements and regulatory filings.

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2024

	NOTES	Year ended De 2024 <i>RMB'000</i>	<b>cember 31,</b> 2023 <i>RMB '000</i>
Revenue Other income Other gains and losses, net Net impairment losses under expected credit loss model Research and development expenses Administrative expenses Selling and marketing expenses Finance costs	4	141,440 (197,665) (50,788) (249,847) (153,155) - (2,366)	$\begin{array}{r} 617\\ 163,728\\ 252,402\\ \hline \\ (402,705)\\ (196,499)\\ (1,419)\\ (494) \end{array}$
Loss before tax Income tax expense	5 6	(512,381)	(184,370)
Loss for the year		(512,381)	(184,370)
Other comprehensive income (expense): Items that will not be reclassified to profit or loss: Exchange differences on translation from functional currency to presentation currency Fair value loss on equity instrument at fair value through other comprehensive income ("FVTOCI")		38,821 (7,920) 30,901	45,305 (19,609) 25,696
Item that may be reclassified subsequently to profit or loss: Exchange differences arising on translation of foreign operations		(706)	(1,013)
Other comprehensive income for the year		30,195	24,683
Total comprehensive expense for the year		(482,186)	(159,687)
Loss for the year attributable to: Owners of the Company Non-controlling interests		(508,162) (4,219) (512,381)	(174,829) (9,541) (184,370)
Total comprehensive expense for the year attributable to: Owners of the Company Non-controlling interests		(477,967) (4,219)	(150,146) (9,541)
Loss nor show		(482,186)	(159,687)
Loss per share – Basic and diluted (RMB)	7	(0.70)	(0.24)

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION** *AT DECEMBER 31, 2024*

		At December 31,	
	NOTES	2024 <i>RMB'000</i>	2023 <i>RMB</i> '000
	NOIES	KIVID UUU	KMD 000
Non-current assets			
Plant and equipment		3,243	2,117
Right-of-use assets Intangible assets		11,055 179,710	3,492 267,420
Financial assets at fair value through profit or loss		179,710	207,420
("FVTPL")		9,198	134,560
Equity instrument at FVTOCI	0	-	7,884
Deposits and other receivables Restricted bank balances	9	71,068 18,229	_
Restricted bank bulances	-	10,227	
		292,503	415,473
	-		
Current assets	0	10.0(2	121 200
Deposits, prepayments and other receivables Restricted bank balances	9	18,962 74,845	121,388 729
Time deposits with original maturity over three months		1,316,950	2,171,011
Cash and cash equivalents		1,003,365	489,650
	-		
	-	2,414,122	2,782,778
Current liabilities			
Other payables	10	55,582	72,081
Lease liabilities	10	4,896	3,156
Deferred income	_	16,943	50,632
		77,421	125,869
	-	<u> </u>	
Net current assets	-	2,336,701	2,656,909
Total assets less current liabilities	-	2,629,204	3,072,382
Non-current liabilities			
Lease liabilities		5,153	_
Note payables	10	17,971	
		23,124	_
	-		
Net assets		2,606,080	3,072,382
Capital and reserves			
Share capital		24	24
Share premium and reserves	-	2,656,933	3,119,016
Equity attributable to owners of the Company		2,656,957	3,119,040
Non-controlling interests		(50,877)	(46,658)
	-		
Total equity	-	2,606,080	3,072,382
	-		

#### **NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS** FOR THE YEAR ENDED DECEMBER 31, 2024

#### 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 addresses of the Company's registered office and principal place of business is PO Box 309, Ugland House, Grand Cayman, KY1 – 1104, Cayman Islands and 3rd Floor, Building 7, Zhongguancun Dongsheng, International Science Park, No. 1 North Yongtaizhuang Road, Haidian District, Beijing, People's Republic of China (the "**PRC**"), respectively.

The Company and its subsidiaries (collectively referred to as the "Group") are committed to advancing therapies for significant infectious diseases and other illnesses which have significant public health burdens in the PRC and worldwide. The Group is based in the PRC, the United States of America (the "USA") and Australia and primarily focused on developing therapies for infectious diseases and central nervous system diseases.

The functional currency of the Company and the operating subsidiary incorporated in the USA is United States Dollars ("US\$"). The functional currency of the PRC and Australia operating subsidiaries is Renminbi ("RMB") and Australian Dollars, respectively. The presentation currency of these consolidated financial statements is RMB as it best suits the needs of the shareholders and investors.

#### 2. APPLICATION OF NEW AND AMENDMENTS TO IFRS ACCOUNTING STANDARDS

#### Amendments to IFRS Accounting Standards that are mandatorily effective for the current year

In the current year, the Group has applied the following amendments to IFRS Accounting Standards issued by the International Accounting Standards Board for the first time, which are mandatorily effective for the Group's annual period beginning on January 1, 2024 for the preparation of these consolidated financial statements:

Amendments to IFRS 16	Lease Liability in a Sale and Leaseback
Amendments to IAS 1	Classification of Liabilities as Current or Non-current
Amendments to IAS 1	Non-current Liabilities with Covenants
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements

The application of these amendments to IFRS Accounting Standards in the current year has had no material impact on the Group's financial positions and performance for the current and prior years and/or on the disclosures set out in these consolidated financial statements.

#### New and amendments to IFRS Accounting Standards in issue but not yet effective

The Group has not early applied the following new and amendments to IFRS Accounting Standards that have been issued but are not yet effective:

Amendments to IFRS 9 and IFRS 7	Amendments to the Classification and Measurement of Financial Instruments <sup>3</sup>
Amendments to IFRS 9 and IFRS 7	Contracts Referencing Nature-dependent Electricity <sup>3</sup>
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its
	Associate or Joint Venture <sup>1</sup>
Amendments to IFRS Accounting Standards	Annual Improvements to IFRS Accounting Standards-Volume 11 <sup>3</sup>
Amendments to IAS 21	Lack of Exchangeability <sup>2</sup>
IFRS 18	Presentation and Disclosure in Financial Statements <sup>4</sup>

<sup>1</sup> Effective for annual periods beginning on or after a date to be determined

- <sup>2</sup> Effective for annual periods beginning on or after January 1, 2025
- <sup>3</sup> Effective for annual periods beginning on or after January 1, 2026
- <sup>4</sup> Effective for annual periods beginning on or after January 1, 2027

Except for the new IFRS Accounting Standard mentioned above, the directors of the Company anticipate that the application of all other amendments to IFRS Accounting Standards will have no material impact on these consolidated financial statements in the foreseeable future.

#### IFRS 18 Presentation and Disclosure in Financial Statements

IFRS 18 *Presentation and Disclosure in Financial Statements*, which sets out requirements on presentation and disclosures in financial statements, will replace IAS 1 *Presentation of Financial Statements*. This new IFRS Accounting Standard, while carrying forward many of the requirements in IAS 1, introduces new requirements to present specified categories and defined subtotals in the statement of profit or loss; provide disclosures on management-defined performance measures in the notes to the financial statements and improve aggregation and disaggregation of information to be disclosed in the financial statements. In addition, some IAS 1 paragraphs have been moved to IAS 8 and IFRS 7. Minor amendments to IAS 7 *Statement of Cash Flows* and IAS 33 *Earnings per Share* are also made.

IFRS 18, and amendments to other standards, will be effective for annual periods beginning on or after January 1, 2027, with early application permitted. The application of the new standard is expected to affect the presentation of the statement of profit or loss and disclosures in the future financial statements. The Group is in the process of assessing the detailed impact of IFRS 18 on the Group's consolidated financial statements.

#### **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 same accounting policies. Accordingly, the Group has only one reportable segment and only entity-wide disclosures are presented.

#### **Geographical information**

At December 31, 2024, the Group has total non-current assets (excluding financial assets at FVTPL, equity instrument at FVTOCI, restricted bank balances and certain deposits and other receivables) of RMB257,325,000 (2023: RMB273,029,000), among which, RMB179,710,000 (2023: RMB191,233,000), RMB489,000 (2023: RMB75,785,000) and RMB77,126,000 (2023: RMB6,011,000) were located in the Cayman Islands, the USA and the PRC, respectively.

During the year ended December 31, 2023, all of the Group's revenue from external customers were located in the PRC.

#### 4. OTHER INCOME

	Year ended De	Year ended December 31,	
	2024	2023	
	RMB'000	RMB'000	
Bank interest income	87,154	108,023	
Government grants (note)	49,936	55,274	
Others	4,350	431	
	141,440	163,728	

*Note:* Government grants including the incentive and other subsidies from government which are specifically for operating activities are recognized upon compliance with the attached conditions. In the current year, government grants of RMB16.2 million (2023: RMB50.0 million) were received. At December 31, 2024, government grants of RMB16.9 million (2023: RMB50.6 million) are recorded as deferred income and will be amortised upon compliance with the relevant conditions.

#### 5. LOSS BEFORE TAX

Year ended December 31,	
2024	2023
RMB'000	RMB'000
2,245	5,228
6,203	8,685
402	1,761
90,348	5,432
2,718	1,906
	2024 <i>RMB'000</i> 2,245 6,203 402 90,348

#### 6. INCOME TAX EXPENSE

The Company is incorporated in the Cayman Islands and subject to Hong Kong profits tax. The Company has no assessable profits for both years.

Brii Biosciences, Inc. is subjected to federal tax rate at 21% and state income tax at rates ranging from 2.5% to 9.9% in the USA.

Brii Biosciences Pty Ltd. is subjected to income tax rate of 25% in Australia.

Pursuant to the Law of the PRC on Enterprise Income Tax (the "EIT Law") and Implementation Regulation of the EIT Law, the tax rate of the PRC subsidiaries is 25%.

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

#### 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:

	Year ended December 31,	
	2024	2023
Loss for the year attributable to owners of the Company for the		
purpose of basic and diluted loss per share (RMB'000)	(508,162)	(174,829)
Weighted average number of ordinary shares for the purpose of		
basic and diluted loss per share ('000)	730,246	728,100

For the years ended December 31, 2023 and 2024, the weighted average number of ordinary shares for the purpose of basic and diluted loss per share excluded the shares held in trust and unvested restricted share units of the Company.

The computation of diluted loss per share for the years ended December 31, 2023 and 2024 did not assume the exercise of share options and the vesting of unvested restricted share units since their assumed exercise and vesting would be anti-dilutive.

#### 8. **DIVIDENDS**

No dividend was paid or declared by the Company during the years ended December 31, 2023 and 2024, nor has any dividend been proposed subsequent to the end of the reporting period.

#### 9. DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

RMB'000RMB'000Prepayments6,59747,685Receivables for prepayments and deposits paid for intangible assets50,788-Rental and other deposits1,3192,613Value-added tax recoverable63,30553,607Interests receivable11,5829,850Deposits paid for acquisition of plant and equipment13-Other receivables7,2147,633Less: impairment loss allowance for other receivables(50,788)-90,030121,388Analysed as:-		At December 31,	
Prepayments6,59747,685Receivables for prepayments and deposits paid for intangible assets50,788-Rental and other deposits1,3192,613Value-added tax recoverable63,30553,607Interests receivable11,5829,850Deposits paid for acquisition of plant and equipment13-Other receivables7,2147,633Less: impairment loss allowance for other receivables(50,788)-90,030121,388Analysed as: Current18,962121,388		2024	2023
Receivables for prepayments and deposits paid for intangible assets50,788Rental and other deposits1,319Rental and other deposits2,613Value-added tax recoverable63,305Interests receivable11,582Deposits paid for acquisition of plant and equipment13Other receivables7,2147,633140,818Less: impairment loss allowance for other receivables(50,788)Analysed as: Current18,962121,388		RMB'000	RMB'000
Rental and other deposits1,3192,613Value-added tax recoverable63,30553,607Interests receivable11,5829,850Deposits paid for acquisition of plant and equipment13-Other receivables7,2147,633Less: impairment loss allowance for other receivables(50,788)-90,030121,388Analysed as: Current18,962121,388	Prepayments	6,597	47,685
Value-added tax recoverable63,30553,607Interests receivable11,5829,850Deposits paid for acquisition of plant and equipment13-Other receivables7,2147,633Less: impairment loss allowance for other receivables(50,788)-90,030121,388Analysed as: Current18,962121,388	Receivables for prepayments and deposits paid for intangible assets	50,788	-
Interests receivable11,5829,850Deposits paid for acquisition of plant and equipment13-Other receivables7,2147,633Less: impairment loss allowance for other receivables(50,788)-90,030121,388Analysed as: Current18,962121,388	Rental and other deposits	1,319	2,613
Deposits paid for acquisition of plant and equipment13Other receivables7,2147,2147,633140,818121,388(50,788)-90,030121,388Analysed as: Current18,962121,388	Value-added tax recoverable	63,305	53,607
Other receivables       7,214       7,633         Less: impairment loss allowance for other receivables       140,818       121,388         (50,788)       -         90,030       121,388         Analysed as:       18,962       121,388	Interests receivable	11,582	9,850
140,818       121,388         (50,788)       -         90,030       121,388         Analysed as:       18,962       121,388	Deposits paid for acquisition of plant and equipment	13	_
Less: impairment loss allowance for other receivables (50,788)	Other receivables	7,214	7,633
Less: impairment loss allowance for other receivables (50,788)		140,818	121,388
Analysed as: Current <b>18,962</b> 121,388	Less: impairment loss allowance for other receivables	,	
Current <b>18,962</b> 121,388		90,030	121,388
Current <b>18,962</b> 121,388	Analysed as:		
Non-current 71,068 –	•	18,962	121,388
	Non-current	71,068	
<b>90,030</b> 121,388		90,030	121,388

#### 10. NOTE AND OTHER PAYABLES

	At December 31,	
	2024 <i>RMB</i> '000	2023 <i>RMB'000</i>
Note payables	17,971	
Payables for research and development expenses Other payables for	7,845	20,539
– legal and professional fee	7,416	1,901
– others	1,458	1,436
Other tax payables	1,189	2,011
Payroll payables	27,810	34,696
Accrued research and development expenses	9,864	11,498
	55,582	72,081
	73,553	72,081
Analysed as:		
Current	55,582	72,081
Non-current	17,971	
	73,553	72,081

The average credit period for purchases of goods/services of the Group is normally within 30 days. 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 Decen	At December 31,	
	2024	2023	
	<i>RMB'000</i>	RMB'000	
0 – 30 days	7,057	15,186	
31 – 60 days	751	4,059	
61 – 90 days	33	1,125	
Over 90 days	4	169	
	7,845	20,539	

The following is an ageing analysis of note payables presented based on the issue date at the end of each reporting period:

	At Decer	At December 31,	
	2024	2023	
	RMB'000	RMB'000	
0 – 360 days	17,971		
0 - 300 days	17,371		

The following is an ageing analysis of note payables presented based on the maturity date at the end of each reporting period:

	At Decen	At December 31,	
	2024	2023	
	RMB'000	RMB'000	
1-2 years	17,971		

# MANAGEMENT DISCUSSION AND ANALYSIS

## **OVERVIEW**

Since our inception, we have diligently pursued breakthrough scientific innovations to tackle major public health challenges. Under the leadership of our seasoned executive team, we are guided by critical patient insights and a global perspective as we advance our robust portfolio of infectious disease candidates.

Our strategic emphasis is on our HBV functional curative therapy program, where we believe there is a substantial opportunity to create a meaningful therapeutic impact for patients both in China and globally. We possess considerable competitive advantages in the pursuit of an HBV cure, driven by our extensive portfolio of assets. We are advancing multiple ongoing HBV studies towards late-stage development: our ENSURE study evaluates elebsiran in combination with PEG-IFN $\alpha$  (including a cohort with BRII-179-experienced patients); our ENRICH study evaluates BRII-179 in priming HBV-specific immunity and enriching patients with competent immunity, followed with elebsiran and PEG-IFN $\alpha$  combination treatment; and our ENHANCE study evaluates the triple combination of BRII-179, elebsiran and PEG-IFN $\alpha$ .

All three of our leading HBV candidates (BRII-179, elebsiran and tobevibart) have been granted Breakthrough Therapy Designation by the CDE, recognizing their potential to deliver substantial advancements over existing therapies and to expedite the clinical development and regulatory review as we strive for a functional cure for HBV. Key data readouts from these studies are planned throughout 2025 and 2026 and will guide our late-stage development and registrational strategy. Our goal is to improve the functional cure rate for broader patient populations through carefully designed combination treatment regimens in responsive or susceptible patients.

Vigorous clinical investigations over the past five years have provided us with essential understanding and unique insights into important factors to sustain HBsAg loss. Building on these data, in 2024, we presented first-time direct evidence that (i) immune responses induced by an HBV therapeutic vaccine (BRII-179) are associated with HBsAg reduction and viral control in certain participants with chronic HBV infection, and (ii) the contribution of siRNA on top of the PEG-IFN $\alpha$  therapy induced higher HBsAg seroclearance than PEG-IFN $\alpha$  alone. These pivotal breakthroughs inform our late-stage clinical combination trials as we execute a clinical strategy to assess and enhance the intrinsic immunity of HBV patients. Our goal is to enrich the lives of those patients who have the best chance of achieving a cure while also sparing others from poorly tolerated treatment regimens.

With approximately RMB2,413.4 million in bank deposits and cash and cash equivalents by the end of 2024, we have sufficient capital to support the late-stage development of our HBV programs through registration. We believe that, through focusing on key programs, we will create value for patients and our Shareholders with capital efficiency.

# **Pipeline Summary**

We have developed an extensive pipeline targeting infectious diseases. Our lead programs are centered on HBV functional cure, primarily in China, the world's largest HBV market.

The table below outlines 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/BLA	Commercial	Our Rights	Partners
	BRII-179		1						Global	-
HBV Curative Treatments(1)	Elebsiran <sup>(2)</sup>		1						Greater China <sup>(5)</sup>	XVir Biotechnology™
	Tobevibart <sup>(3)</sup>		5						Greater China <sup>(5)</sup>	XVir Biotechnology™
HIV Long-Acting	BRII-732		) 1						Global	
	BRII-753						: :		Global	-
MDR/XDR Gram-negative Bacterial Infections	BRII-693								Global	-
NTM Lung Disease	Epetraborole <sup>(4)</sup>								Greater China <sup>(5)</sup>	<b>AN2</b> Therapeutics

- (1) The Phase 2 combination clinical trials conducted by Brii Bio:
  - ENSURE study: Elebsiran + PEG-IFNα vs PEG-IFNα alone
  - ENRICH study: BRII-179  $\rightarrow$  elebsiran + PEG-IFN $\alpha$
  - ENHANCE study: BRII-179 + elebsiran + PEG-IFNα
- (2) Elebsiran was previously known as BRII-835 or VIR-2218.
- (3) Tobevibart was previously known as BRII-877 or VIR-3434. The Phase 2 clinical trials have been conducted by Vir Biotechnology.
- (4) Epetraborole was previously known as BRII-658. To this date, the development and clinical trials have been conducted by AN2.
- (5) Greater China Mainland China, Macau, Hong Kong and Taiwan.

#### **BUSINESS REVIEW**

We continuously advanced our product pipeline and business operations during the Reporting Period. As we move our leading HBV candidates into late-stage clinical development, we have strategically increased our investments in these assets.

We successfully progressed multiple clinical trials and presented critical datasets, offering valuable insights that support further clinical evaluation of elebsiran and BRII-179 in combination with other modalities (such as siRNA and PEG-IFN $\alpha$ ) for achieving a functional cure for chronic HBV infection. We presented EOT data from the ENSURE study at the 2024 AASLD The Liver Meeting<sup>®</sup>, demonstrating that siRNA in combination with PEG-IFN $\alpha$  achieved higher HBsAg seroclearance than PEG-IFN $\alpha$  alone. At the European Association for the Study of the Liver Congress 2024, we presented data from a Phase 2 study showing direct evidence for the first time that immune responses induced by an HBV therapeutic vaccine are associated with HBsAg reduction and viral control in certain participants with chronic HBV infection.

Upcoming critical datasets from our ongoing ENSURE (elebsiran in combination with PEG-IFN $\alpha$  versus PEG-IFN $\alpha$  alone), ENRICH (BRII-179 in priming HBV-specific immunity) and ENHANCE (concurrent combination of BRII-179, BRII-835 and PEG-IFN $\alpha$ ) studies are expected throughout 2025 and 2026 and will further inform our late-stage studies as we advance towards our goal of determining the most optimal HBV functional cure for targeted populations.

With our strategic focus on HBV, we are actively exploring partnerships to further develop our promising programs in MDR/XDR and HIV.

As of the date of this announcement, our key achievements, along with our planned next steps and upcoming milestones, include:

#### **Core Clinical Pipeline Highlights and Upcoming Milestones**

#### Hepatitis B Virus Program Development Updates

Led by its team in China, the Company is advancing multiple combination studies for the treatment of HBV to enhance the probability of achieving a high rate of functional cure for chronic HBV patients in China. China has the largest prevalence of HBV in the world, with around 87 million people impacted by this disease, yet there is no effective functional cure currently available for these patients.

# **BRII-179 Related Studies and Plans**

**BRII-179** 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. In December 2024, the Company signed an asset purchase agreement with VBI to acquire the full intellectual property rights of BRII-179.

- Cohort 4 of the ENSURE study is investigating patients with prior experience receiving BRII-179. Based on early data from Cohort 4 (data to be released at the APASL 2025 in March 2025), the Company initiated the ENRICH study, evaluating the role of BRII-179 in priming HBV-specific immunity as part of a curative regimen and as a tool to identify immunoresponsive patients with a higher probability of achieving a functional cure. The study was fully enrolled in November 2024.
- In June 2024, the Company presented data from two Phase 2 studies at the EASL<sup>TM</sup> Congress 2024, demonstrating that BRII-179, administered in combination with elebsiran, induced substantial HBV-specific B and T cell responses that correlate with an antiviral effect. Additionally, BRII-179, administered on top of PEG-IFNα, improved the overall HBsAg loss rate. These results contribute to a growing body of evidence supporting BRII-179's ability to enhance HBV functional cure rate in combination with other modalities.

# Elebsiran and Tobevibart Related Studies and Plans

**Elebsiran** is an investigational subcutaneously administered HBV-targeting siRNA designed to degrade hepatitis B virus RNA transcripts and limit the production of hepatitis B surface antigen. It has the potential to have direct antiviral activity against HBV and HDV. It is the first siRNA in the clinic to include Enhanced Stabilization Chemistry Plus technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index. We licensed exclusive rights to develop and commercialize elebsiran for the Greater China territory from Vir Biotechonology in 2020.

**Tobevibart** is an investigational subcutaneously administered HBV-neutralizing monoclonal antibody designed to block entry of HBV and HDV into hepatocytes and to reduce the level of virions and subviral particles in the blood. The Fc domain of tobevibart has been engineered to increase immune engagement and clearance of HBsAg immune complexes, and incorporates Xencor's Xtend<sup>TM</sup> technology to extend half-life. We licensed exclusive rights to develop and commercialize tobevibart for the Greater China territory from Vir Biotechonology in 2022.

- Throughout 2025 to 2026, the Company plans to introduce datasets for its ongoing combination studies to evaluate the potency of different combination treatment regimens containing BRII-179, elebsiran and PEG-IFN $\alpha$ , including the ENSURE, ENRICH and ENHANCE studies.
- The Company completed enrollment in its ENHANCE study in January 2025. The ENHANCE study is a Phase 2b, randomized, double-blind study evaluating the clinical efficacy and safety of the combination therapy of BRII-179 and elebsiran, plus PEG-IFN $\alpha$  compared to PEG-IFN $\alpha$  in adult participants with chronic HBV infection without cirrhosis receiving nucleos(t)ide reverse transcriptase inhibitors as background therapy.

- The Company presented 48-week EOT data from its Phase 2 ENSURE study at the AASLD The Liver Meeting<sup>®</sup> in a late-breaking oral presentation in November 2024. Data showed patients treated with elebsiran in combination with PEG-IFN $\alpha$  achieved a higher rate of HBV surface antigen loss than patients treated with PEG-IFN $\alpha$  alone. The ENSURE study data suggest the industry's first evidence delineating the contribution of siRNA (elebsiran) towards functional cure on top of PEG-IFN $\alpha$  therapy through head-to-head comparison with PEG-IFN $\alpha$  alone, highlighting elebsiran's potential to make a substantial impact on producing a higher HBV functional cure rate. The Company plans to present additional key data readouts from its ENSURE study in the first half of 2025.
- The Company's development partner, Vir Biotechnology, presented data from its Phase 2 studies MARCH (evaluating tobevibart in combination with elebsiran, with or without PEG-IFN $\alpha$  for the treatment of chronic HBV) and SOLSTICE (evaluating tobevibart alone or in combination with elebsiran for the treatment of CHD) at the AASLD The Liver Meeting<sup>®</sup> in November 2024. Vir Biotechnology announced in March 2025 the start of a Phase 3 registrational clinical program (ECLIPSE) to evaluate the combination of tobevibart and elebsiran in people living with CHD.
- A Phase 1 study of tobevibart was completed in China, comparing human pharmacokinetics in mainland Chinese subjects with those from other APAC regions and Europe.
- In 2024, tobevibart and elebsiran were granted BTD by China's NMPA, and Fast Track designations for the treatment of CHD. Also, Vir Biotechnology was granted BTD for tobevibart and elebsiran for the treatment of CHD by the U.S. FDA and Orphan and Prime designations by the EMA.

## Additional Clinical and Pre-Clinical Development Updates

In line with the Company's strategy to focus on its advanced HBV cure programs, the low priority programs have been paused and the development of the MDR/XDR and HIV programs of the Company is contingent on external partnership.

# Multidrug- and Extensively Drug-Resistant Gram-Negative Bacteria Infections Program

**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 for the treatment of critically ill patients with gram-negative bacterial infections. 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. We hold exclusive global rights to develop and commercialize BRII-693.

The U.S. FDA has granted BRII-693 designation as a QIDP, which offers various incentives for its development in the U.S., including priority review and eligibility for the U.S. FDA's Fast Track designations. This designation also opens the possibility for extended regulatory and market exclusivity in the U.S.

• In October 2024, Brii Bio received IND approval from the CDE for a Phase 1 PK bridging study in China with BRII-693, a novel polymyxin for the treatment of serious gram-negative infections. Previous Phase 1 data was published in *Antimicrobial Agents and Chemotherapy* in December 2024 to support a global Phase 3 registrational trial in patients with hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia.

# HIV Infection Program

**BRII-753** is an NRTTI, which is an internally discovered NCE prodrug of EFdA currently in the pre-clinical stage of development. It is being developed as a long-acting subcutaneous injection with the potential to be given once monthly, once quarterly, or twice yearly. It can be used as a combination therapy for HIV treatment and as monotherapy for pre-exposure prophylaxis.

**BRII-732** is a proprietary NCE prodrug that, upon oral administration, is rapidly metabolized into EFdA and is under evaluation as a potential HIV treatment or prevention option. EFdA is an NRTTI, acting as both a chain terminator and translocation inhibitor of HIV. BRII-732 has completed Phase 1 studies with the potential for development as part of an oral, once-weekly, long-acting combination treatment option for HIV patients.

# NTM Lung Disease Program

**Epetraborole** (**previously known as BRII-658**) 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 in the Greater China.

• The Company's partner, AN2, has provided an update from its ongoing analysis of the Phase 2 portion of the epetraborole Phase 2/3 study. The findings are particularly noteworthy given the severe refractory status of the patients studied and the fact that two potential clinical endpoints achieved nominally statistical significance. AN2 has revised the statistical analysis plan to elevate one of the two clinical endpoints to the primary efficacy endpoint and plans to unblind the Phase 3 portion of the trial in the second quarter of 2025. Should the Phase 3 recapitulate the Phase 2 data, AN2 will seek a meeting with the U.S. FDA to seek pathways toward registration.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ANY OF THE ABOVE PRE-CLINICAL STAGE OR CLINICAL STAGE DRUG CANDIDATES SUCCESSFULLY.

# **Other Corporate Developments**

- In December 2024, the Company announced the approval of a HK\$60 million sharebuyback program to buy back Shares not exceeding 10% of the total number of issued Shares (excluding treasury shares (as defined under the Listing Rules)) as at June 25, 2024, underscoring the Company's confidence in its prospects. As of the date of this announcement, the Company had repurchased approximately 4,433,000 Shares on the Stock Exchange for a consideration of approximately HK\$5.3 million.
- In December 2024, the Company signed an asset purchase agreement with, among others, VBI and its subsidiaries to acquire full intellectual property rights and other assets relating to BRII-179 for a total consideration of US\$18 million. The agreement eliminates future payments to VBI related to BRII-179 and PreHevbri<sup>™</sup> and terminates the prior agreements announced on February 14, 2024. The purchase brings to the Company additional commercial upside while ensuring the uninterrupted clinical supply of BRII-179 as the Company continues to develop this asset with ongoing studies that support BRII-179's potential to increase HBV patients' response to curative treatments.

## **Research and Development**

We are a biotech company primarily engaged in pharmaceutical R&D activities. We recognize that R&D is fundamental for shaping our therapeutic strategy and sustaining our competitiveness in the biopharmaceutical industry. We prioritize diseases based on patients' needs, aiming to provide viable solutions to prevalent infectious diseases.

Our R&D capabilities, both in-house and through collaborations, enable us to identify and innovate therapies for both the Chinese and international markets. Led by industry veterans, our in-house R&D team is supported by a strong scientific advisory board and strategic partnerships with global pharmaceutical and biotech companies, along with contract research organizations, contract manufacturing organizations, contract development and manufacturing organizations, and research institutions. With our competitive advantage in cross-border and organic operations, we plan to further enhance our capacity and capabilities.

Our R&D executive team includes Chief Executive Officer Dr. Zhi Hong, Chief Medical Officer Dr. David Margolis, Chief Scientific Officer Dr. Brian A. Johns, Chief Technology Officer Dr. Ellee de Groot and Head of China R&D Dr. Qing Zhu. Our esteemed Board and scientific advisory board members, who possess diverse industry expertise and a proven record in successful drug development, direct our R&D processes and candidate selection through their extensive knowledge across various disciplines.

Our multi-pronged R&D strategies are designed with flexibility in mind, resulting in expenses that vary according to the number and scale of projects each year. Our R&D expenses for the year ended December 31, 2024 amounted to RMB249.8 million. We remain committed to leveraging our technology and R&D capabilities to broaden our life sciences research and application capabilities and product candidate portfolio.

# Commercialization

Our pipeline includes therapeutic candidates, encompassing both programs with global rights and with in-licensed Greater China rights.

As of the date of this announcement, our efforts have primarily focused on developing our therapeutic candidate pipeline. Most of our programs are in various stages of clinical development, and we do not anticipate sales or commercialization of drug candidates in the immediate future. As our pipeline gradually matures, we will evaluate strategic commercialization options, ensuring that we maximize their potential in addressing critical unmet medical needs.

## **FUTURE DEVELOPMENT**

In alignment with our corporate strategy devoted to alleviating public health burdens and improving patients' experiences through developing innovative treatment options, we strive to further advance our diverse pipeline by leveraging our in-house capabilities while exploring external partnerships.

As a leading company in the field of HBV functional cure, we will maintain our focus on increasing the functional cure rate through various combination therapies. We will further evaluate our combination treatment regimens under development, aiming for a higher functional cure rate for HBV infection by leveraging the additional data available from several ongoing trials. We also plan to initiate definitive clinical studies to bring a combination treatment regimen to the next stage of development in the Greater China. As our HBV candidates are approaching late-stage development, we are establishing a strategic and cost-effective manufacturing and supply chain management plan.

For our other programs, we are seeking partnerships for continued development, allowing us to optimize our resources and concentrate on our promising core HBV program.

Our long-term strategy focuses on expanding our pipeline through in-house discovery and strategic licensing opportunities. We aim to explore business development opportunities, especially the opportunities for out-licensing our internally discovered therapeutic candidates for international markets. As we embark on our second five-year period, we have refined our discovery strategy to align more closely with our long-term pipeline interests, priorities and overall vision. To ensure sustainable development, we will continue to optimize our organization to foster innovation and enhance our business development efforts, all in line with our mission to tackle the world's biggest public health challenges.

#### SUBSEQUENT EVENTS

Save as disclosed in this announcement, the Directors are not aware of any significant event requiring disclosure that has taken place subsequent to December 31, 2024 and up to the date of this announcement.

# FINANCIAL REVIEW

#### 1. Other income

	Year ended December 31,		
	<b>2024</b> 202		
	RMB'000	RMB'000	
Bank interest income	87,154	108,023	
Government grants	49,936	55,274	
Others	4,350	431	
Total	141,440	163,728	

Our other income was decreased by RMB22.3 million from RMB163.7 million for the year ended December 31, 2023 to RMB141.4 million for the year ended December 31, 2024. This was mainly due to the decrease in bank interest income of RMB20.8 million attributable to the declining interest rates on USD and HKD time deposits and the RMB5.4 million decrease in recognized income from government grants. These grants mainly represent the incentive and other subsidies from the PRC government which are intended to incentivize R&D activities and are recognized upon compliance with the attached conditions.

#### 2. Other gains and losses

Our other gains and losses were decreased by RMB450.1 million from gains of RMB252.4 million for the year ended December 31, 2023 to losses of RMB197.7 million for the year ended December 31, 2024. The decrease was of non-cash nature and primarily attributable to the fair value loss on financial assets and the impairment loss recognized on intangible assets.

#### 3. Fair value loss on equity instruments at FVTOCI

Our fair value loss on equity instruments at FVTOCI was decreased by RMB11.7 million from loss of RMB19.6 million for the year ended December 31, 2023 to loss of RMB7.9 million for the year ended December 31, 2024. The amount represents the equity investment in a biopharmaceutical company in the USA. As the biopharmaceutical company was delisted from NASDAQ Global Market on August 8, 2024, the fair value of the equity investment was determined to be zero. Subsequent to the Reporting Period, this biopharmaceutical company completed a restructuring proceeding under the Companies' Creditors Arrangement Act (Canada) and as a result, the Group no long holds any equity interest in this company.

#### 4. Research and development expenses

	Year ended December 31,		
	<b>2024</b> 2		
	RMB'000	RMB'000	
Third-party contracting cost	139,145	218,363	
Employee cost	107,057	174,815	
Amortization	127	1,358	
Others	3,518	8,169	
Total	249,847	402,705	

Our research and development expenses were decreased by RMB152.9 million from RMB402.7 million for the year ended December 31, 2023 to RMB249.8 million for the year ended December 31, 2024. The decrease was primarily attributable to the decrease in third-party contracting cost of RMB79.3 million and the decrease in employee cost of RMB67.7 million as the Company prioritizes HBV functional cure program and has strategically optimized its organization.

#### 5. Administrative expenses

	Year ended December 31,		
	2024		
	<i>RMB'000</i>	RMB'000	
Employee cost	86,843	126,498	
Professional fees	32,662	27,117	
Depreciation and amortization	8,723	14,316	
Office expenses	3,909	4,489	
Others	21,018	24,079	
Total	153,155	196,499	

Our administrative expenses were decreased by RMB43.3 million from RMB196.5 million for the year ended December 31, 2023 to RMB153.2 million for the year ended December 31, 2024. This was primarily attributable to the decrease in employee cost of RMB39.7 million from RMB126.5 million for the year ended December 31, 2023 to RMB86.8 million for the year ended December 31, 2024, which was primarily attributable to organizational optimization.

#### 6. Liquidity and Capital resources

As of December 31, 2024, our bank and cash balances, including restricted bank balances and time deposits, decreased to RMB2,413.4 million from RMB2,661.4 million as of December 31, 2023. The decrease was primarily due to payout of daily operations and third-party contracting costs.

#### 7. 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 year 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 year represents the loss for the year excluding the effect of certain noncash items, namely share-based compensation expenses. The term adjusted loss for the year 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 year-to-year and company-to-company to the extent applicable.

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

	Year ended December 31,		
	2024 <i>RMB</i> '000	2023 <i>RMB</i> '000	
Loss for the year Added: Share-based compensation	(512,381)	(184,370)	
	16,051	64,223	
Adjusted loss for the year	(496,330)	(120,147)	

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

	Year ended December 31,		
	2024 <i>RMB'000</i>	2023 <i>RMB</i> '000	
Research and development expenses for the year Added:	(249,847)	(402,705)	
Share-based compensation	1,326	29,756	
Adjusted research and development expenses for the year	(248,521)	(372,949)	

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

	Year ended December 31,		
	2024 <i>RMB'000</i>	2023 <i>RMB</i> '000	
Administrative expenses for the year Added:	(153,155)	(196,499)	
Share-based compensation	14,725	37,306	
Adjusted administrative expenses for the year	(138,430)	(159,193)	

## 8. Key financial ratios

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

	As at December 31, 2024	
Current ratio <sup>(1)</sup>	3,118%	2,211%
Gearing ratio <sup>(2)</sup>	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 and deferred income as we have paid out most of the payables for third-party contracting cost and most of the deferred income has been amortized during the year.
- (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 our interest-bearing borrowings less cash equivalents was negative.

## 9. Indebtedness

#### **Borrowings**

As at December 31, 2024, other than the note payables of RMB18.0 million, 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 December 31, 2024, 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 December 31, 2024, the Group had lease liabilities of RMB10.0 million recognized under IFRS 16.

#### 10. Significant Investments, Material Acquisitions and Disposals

As at December 31, 2024, we did not hold any significant investments. For the year ended December 31, 2024, we did not have material acquisitions or disposals of subsidiaries, associates, and joint ventures.

#### **11.** Charge on the Group's Assets

As at December 31, 2024, none of the Group's assets were charged with any parties or financial institutions (as at December 31, 2023: nil).

## 12. 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 December 31, 2024, the Group's restricted bank deposits, time deposits with original maturity over three months and bank balances and cash were denominated as to 48.1% in US dollars, 35.1% in Hong Kong dollars, 16.6% in RMB and 0.2% in Australian Dollars.

## **13.** Employees and remuneration

As at December 31, 2024, we had a total of 98 employees. The following table sets forth the total number of employees by function as of December 31, 2024:

Function	Number of employees	% of total
Research and development Administration	67 31	68% 32%
Total	98	100%

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. We conducted portfolio optimization in early 2024. We decided to seek partnership for our non-HBV clinical programs and would not further invest internal resources on these programs. As a result, we implemented a reduction in force in our U.S. organization.

The total remuneration cost incurred by the Group for the year ended December 31, 2024 was RMB194 million, representing a decrease of 36%, compared with RMB302 million for the year ended December 31, 2023.

# 14. 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 comparable to the interest rate of current bank deposits, with an emphasis on preserving principal and maintaining liquidity.

#### **OTHER INFORMATION**

# USE OF NET 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). During the Reporting Period, the Company had utilized such net proceeds in accordance with the purposes as set out in the Prospectus (as subsequently revised and disclosed in the annual results announcement of the Company dated March 24, 2023 (the "Announcement")).

As of December 31, 2024, our Company has not yet fully utilized the net proceeds from the Global Offering (the "**Net Proceeds**") of approximately HK\$1,082.3 million (the "**Unutilized Net Proceeds**").

# Change in Use of Proceeds from the Global Offering

The Board, having considered the reasons set out in "Reasons for the Change in Use of Proceeds" below, resolved to change the use of the Unutilized Net Proceeds after the Reporting Period. The planned applications of the Net Proceeds as disclosed in the Announcement, the actual usage up to December 31, 2024, and the proposed change and the revised allocation of the Net Proceeds and Unutilized Net Proceeds are set out in the table below:

Original use of proceeds as disclosed in the Announcement	Original allocation of Net Proceeds as disclosed in the Announcement (HK\$ million)	Original percentage of total Net Proceeds as disclosed in the Announcement	Amount of utilized Net Proceeds during the Reporting Period (HK\$ million)	Amount of Unutilized Net Proceeds as at December 31, 2024 (HK\$ million)	Amount of utilized Net Proceeds as at December 31, 2024 ( <i>HK</i> \$ million)	Changed use of proceeds	Revised allocation of Net Proceeds (HK\$ million)	Revised percentage of total Net Proceeds	Revised amount of Unutilized Net Proceeds as at December 31, 2024 (HK\$ million)
1. Used for our HBV functional cure	994.1	38%	182.5	312.3	681.8	1. Same as original	1,466.6	56%	784.8
programs 1.1 To fund ongoing and planned clinical trials and preparation for regulatory filings for developing combination regimens containing BRII-179, BRII-835 or BRII-877	837.3	32%	182.5	155.5	681.8	1.1 Same as original	1,195.9	46%	514.1
1.2 Used for regulatory milestone payments for BRII-179	26.1	1%	-	26.1	-	1.2 Used for IP related payments for BRII-179	140.0	5%	140.0
1.3 Used for the launch and commercialization of HBV curative treatment regimens	130.7	5%	-	130.7	-	1.3 Same as original	130.7	5%	130.7
<ol> <li>Used for our HIV programs, funding the ongoing and planned non-clinica studies, clinical trials and preparatio for registration filings for BRII-732 and BRII-753</li> </ol>		7%	5.3	24.3	151.7	2. Same as original	151.7	6%	-
3. Used for our MDR/XDR gram-	294.0	11%	14.6	226.5	67.5	3. Same as original	67.5	3%	-
negative infections programs 3.1 To fund the ongoing and planned clinical trials and preparation for registration filings for BRII-636, BRII-672 and BRII-693	234.5	9%	14.6	175.5	59.0	3.1 Same as original	59.0	2%	-
3.2 Used for regulatory milestone payments for BRII-636, BRII-672 and BRII-693	59.5	2%	-	51.0	8.5	3.2 Same as original	8.5	0%	-
<ol> <li>Used for our CNS programs, funding the ongoing and planned non-clinica studies, clinical trials and preparatio for registration filings for BRII- 296, BRII-297 and other pre-clinical clinical candidates</li> </ol>	1	19%	38.1	221.7	274.6	4. Same as original	274.6	11%	-
<ol> <li>Used for discovery and business development activities for pipeline expansion</li> </ol>	392.0	15%	20.5	297.5	94.5	5. Same as original	392.0	15%	297.5
<ol> <li>Used for working capital and genera corporate purposes</li> </ol>	261.4	10%	-	-	261.4	6. Same as original	261.4	10%	-
Total	2,613.8	100%	261.0	1,082.3	1,531.5	Total	2,613.8	100%	1,082.3

The Company expects to fully utilize the Unutilized Net Proceeds after the proposed change by the end of 2027.

## **Reasons for the Change in Use of Proceeds**

The reasons for the above changes in the proposed applications of the Net Proceeds and reallocation of the Unutilized Net Proceeds are as follows:

- a) The Company has prioritized resources to focus on the clinical and commercial development of its advanced HBV portfolio and is progressing multiple ongoing combination studies with its differentiated HBV candidates. Following the pipeline prioritization decision, the further development of its HIV, MDR/XDR and CNS programs is contingent on external partnership opportunities. Therefore, the portion of the Unutilized Net Proceeds allocated to original items 2, 3, and 4 are adjusted downwards and re-allocated to revised item 1.1.
- b) The Company entered into an agreement with VBI Vaccines, Inc. and certain of its subsidiaries (collectively, "VBI"), its creditor K2 VBI Equity Trust, LLC and K2 HealthVentures LLC, acquiring the intellectual property and other assets relating to BRII-179 in December 2024. Under the agreement, the Company fully acquired the BRII-179 patents, BRII-179 know-how, and relevant BRII-179 materials, eliminating all future milestones payable to VBI. Therefore, original item 1.2 has been updated to reflect the change in the nature of BRII-179 related payments.

The Board confirms that there is no material change in the business nature of the Company as set out in the Prospectus, and considers that the above changes in the use of the Unutilized Net Proceeds is fair and reasonable as this would allow the Company to deploy its financial resources more effectively and efficiently, will not have any material adverse impact on the operations of the Company, and is therefore in the best interests of the Company and the Shareholders as a whole.

Save as the changes disclosed above, there are no other proposed changes in the use of the Net Proceeds. The Unutilized Net Proceeds will be applied in a manner consistent with the above planned applications and remains subject to change based on the current and future development of market conditions and our actual business needs.

# FINAL DIVIDEND

The Board did not recommend the payment of a final dividend for the year ended December 31, 2024.

#### **CLOSURE OF THE REGISTER OF MEMBERS**

The Company will hold the AGM on Tuesday, June 17, 2025. The register of members of the Company will be closed from Thursday, June 12, 2025 to Tuesday, June 17, 2025, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend and vote at the AGM, during which no share transfers will be registered. To be eligible to attend and vote at the AGM, all properly completed transfer forms accompanied by the relevant share certificates must be lodged for registration with the Company's branch share registrar in Hong Kong, Tricor Investor Services Limited, at 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong not later than 4:30 p.m. on Wednesday, June 11, 2025. Shareholders whose names appear on the register of members of the Company on Tuesday, June 17, 2025 are entitled to attend and vote at the AGM.

#### **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 CG Code contained in Appendix C1 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 R&D 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 power and authority is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises two executive Directors 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 C3 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, including sales of treasury shares (as defined in the Listing Rules). As at December 31, 2024, the Company did not hold any treasury shares (as defined in the Listing Rules).

# AUDIT AND RISK COMMITTEE

The Board has established the Audit and Risk Committee which comprises three independent non-executive Directors, namely Ms. Grace Hui Tang, Mr. Yiu Wa Alec Tsui and Dr. Taiyin Yang. 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 and 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 risk management and internal control system and financial reporting matters of the Group (including the review of the consolidated financial statements of the Group for the year ended December 31, 2024), and is of the view that the annual results of the Group for the year ended December 31, 2024 is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

## SCOPE OF WORK OF MESSRS. DELOITTE TOUCHE TOHMATSU

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2024 as set out in this announcement have been agreed by the auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the audited consolidated financial statements of the Group for the year as approved by the Board on March 21, 2025. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by Messrs. Deloitte Touche Tohmatsu on this announcement.

# **ADDITIONAL INFORMATION**

# Passive Foreign Investment Company ("PFIC") Status

Based on the nature and composition of our income, assets and activities for our taxable year ending December 31, 2024, and certain assumptions with respect to the characterization of our income and assets as active or passive, the Company was classified as a PFIC for our taxable year ending December 31, 2024. If we are classified as a PFIC in any taxable year, a U.S. Holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A notification letter addressed to our U.S. Holder, containing the available PFIC annual information statements for the year ended December 31, 2024 will be published on the website of the Stock Exchange in a separate announcement. For details of the impact and relevant guidance for action as our U.S. Holder of PFIC, please refer to the announcement of the Company dated March 22, 2024.

# PUBLICATION OF THIS ANNUAL RESULTS ANNOUNCEMENT AND THE ANNUAL REPORT

This annual results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.briibio.com). The annual report of the Company for the year ended December 31, 2024 containing all the information required by the Listing Rules will be dispatched, if necessary, 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.

"AASLD"	the American Association for the Study of Liver Diseases
"AGM"	the annual general meeting of the Company to be held on Tuesday, June 17, 2025
"AN2"	AN2 Therapeutics, Inc., a corporation incorporated in Delaware, U.S., whose stocks are listed on the NASDAQ Global Select Market (NASDAQ: ANTX)
"APAC"	Asia Pacific
"APASL"	the Asian Pacific Association for the Study of Liver
"Audit and Risk Committee"	the audit and risk committee of the Board
"BLA"	biologics license application
"Board"	the board of directors of the Company
"BTD"	Breakthrough Therapy Designation
"CDE"	the Center for Drug Evaluation of the NMPA of China
"CG Code"	the Corporate Governance Code contained in Appendix C1 to the Listing Rules
"CHD"	chronic hepatitis D
"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
"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 (腾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
"Director(s)"	director(s) of the Company
"EASL"	European Association for the Study of the Liver
"EFdA"	an NRTTI and an investigational drug for the treatment of HIV infection
"ЕМА"	the European Medicines Agency
"ENHANCE study"	a study to evaluate the efficacy and safety of combination therapy of BRII-179, elebsiran and PEG-IFN $\alpha$ in participants with chronic HBV infection
"ENSURE study"	a study to investigate the efficacy and safety of elebsiran and PEG-IFN $\alpha$ combination therapy in chronic HBV patients
"ENRICH study"	a study to investigate the efficacy and safety of regimens containing BRII-179, elebsiran, and PEG-IFN $\alpha$ treating chronic HBV infection
"ЕОТ"	end-of-treatment
"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
"HBsAg"	hepatitis B surface antigen
"HBV"	hepatitis B virus
"HDV"	hepatitis D virus
"HIV"	human immunodeficiency virus
"Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China
"HK\$" or "HKD"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"IFRS"	International Financial Reporting Standard

"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or clinical trial notification in Australia
"IP"	intellectual property
"Listing Rules"	the Rules Governing the Listing of Securities on the Stock Exchange
"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 C3 to the Listing Rules
"MDR/XDR"	multi-drug resistant/extensive drug resistant
"NCE"	new chemical entity
"NDA"	new drug application
"NMPA"	the National Medical Products Administration
"NRTTI"	nucleoside analogue reverse transcriptase translocation inhibitor
"NTM"	nontuberculous mycobacteria
"PEG-IFNα"	pegylated interferon alfa
"РК"	pharmacokinetics
"Prospectus"	the prospectus of the Company dated June 30, 2021
"QIDP"	Qualified Infectious Disease Product
"Reporting Period"	the year ended December 31, 2024
"RMB"	Renminbi, the lawful currency of the PRC
"RNA"	ribonucleic acid
"R&D"	research and development
"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" 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

"U.S. Holder" a holder who, for U.S. federal income tax purposes, is a beneficial owner of our Shares and is: (i) a citizen or individual resident of the United States; (ii) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or (iv) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations

"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 Biotechnology" 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, March 21, 2025

As at the date of this announcement, the Board comprises Dr. Zhi Hong and Dr. Ankang Li as executive Directors; and Dr. Martin J Murphy Jr, Ms. Grace Hui Tang, Mr. Yiu Wa Alec Tsui, Mr. Gregg Huber Alton and Dr. Taiyin Yang as independent non-executive Directors.