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Brii Biosciences Limited
騰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, 2023

The Board is pleased to announce the consolidated annual results of the Group for the year ended December 31, 2023, 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 RMB2,661.4 million as of December 31, 2023, representing a decrease of 337.9 million or 11.3%, compared with RMB2,999.3 million as of December 31, 2022. The decrease was primarily due to payout of daily operations and research and development activities.
- Other income was RMB163.7 million for the year ended December 31, 2023, representing an increase of RMB55.8 million or 51.7%, compared with RMB107.9 million for the year ended December 31, 2022. This was mainly due to the increased bank interest income of RMB70.8 million attributable to the rising interest rates on USD and HKD time deposits. The increase was partially offset by the decrease in income recognized from PRC government grants.
- Research and development expenses were RMB402.7 million for the year ended December 31, 2023, representing a decrease of RMB37.9 million or 8.6%, compared with RMB440.6 million for the year ended December 31, 2022. The decrease was primarily due to the discontinuation of COVID-19 programs.
- Administrative expenses were RMB196.5 million for the year ended December 31, 2023, representing an increase of RMB27.9 million or 16.5%, compared with RMB168.6 million for the year ended December 31, 2022. The increase was primarily attributable to the increase in employee cost.
- Total comprehensive expenses were RMB159.7 million for the year ended December 31, 2023, representing a decrease of RMB78.8 million or 33.0%, compared with RMB238.5 million for the year ended December 31, 2022. The decrease was primarily attributable to the increase in other gain and loss, which was partially offset by the decrease in gain arising from the exchange differences on translation from functional currency to presentation currency.

BUSINESS HIGHLIGHTS

During the Reporting Period, Brie Bio achieved significant milestones across its diverse portfolio, notably advancing its lead hepatitis B virus program. With ongoing combination studies and strategic partnerships, we are vigorously working to cement the position of our proprietary therapeutic vaccine, BR11-179, in HBV treatment, aiming for a substantial improvement in the HBV functional cure rate. Building on key data readouts as well as the acquisition of intellectual property rights and technology transfer for BR11-179, Brie Bio is primed to launch additional combination studies in 2024.

In February 2024, the Company entered into several agreements with VBI, VBI Cda and SciVac to secure full intellectual property rights for BR11-179 and eliminate all future payment obligations of the Company under the previous collaboration agreements entered into between the parties. Brie Bio has also taken steps to enhance its manufacturing capabilities by acquiring the technology transfer and facility of BR11-179/PreHevbri™ in Rehovot. These transactions are intended to support the advancement of our late-stage HBV program as well as expand our future supply capacity and internal manufacturing capabilities.

Concurrently, our ongoing efforts in earlier stage programs targeting multidrug-resistant and extensively drug-resistant Gram-negative infections, continue to progress as we own global rights and actively seek strategic partnership. The Company is also exploring partnership opportunities for its therapeutic candidates in human immunodeficiency virus and postpartum depression/major depressive disorders, ensuring HBV remains a top priority.

Additionally, the Company has strategically optimized its organizational structure and realigned its executive team to maximize internal resource allocation to ensure sustainable long-term growth. With these corporate framework adjustments alongside the business development transactions in mid-2023, the Company has retained a robust cash reserve of US\$376 million, providing substantial financial backing to sustain its operations until 2027.

Looking forward, the Company is ready to initiate late-stage clinical trials for its HBV functional cure program, also considering factors such as scientific differentiation, commercialization pace, and the potential for best-in-class effectiveness. Additionally, we will actively pursue external collaboration to advance the clinical development of our MDR/XDR, HIV and CNS programs, while also focusing on the commercialization of PreHevbri™ in the APAC regions. Furthermore, we are working to refine our discovery strategy, placing heightened emphasis on platforms and disease areas aligning with our long-term pipeline interests, priorities, and strategic objectives.

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.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2023

		Year ended December 31,	
		2023	2022
	NOTES	RMB'000	RMB'000
Revenue	4	617	51,626
Other income	5	163,728	107,857
Other gains and losses, net		252,402	(12,289)
Research and development expenses		(402,705)	(440,634)
Administrative expenses		(196,499)	(168,629)
Selling and marketing expenses		(1,419)	(26,861)
Finance costs		(494)	(851)
		<u> </u>	<u> </u>
Loss before tax	6	(184,370)	(489,781)
Income tax expense	7	—	—
		<u> </u>	<u> </u>
Loss for the year		<u>(184,370)</u>	<u>(489,781)</u>
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		45,305	297,388
Fair value loss on equity instrument at fair value through other comprehensive income (“FVTOCI”)		(19,609)	(30,110)
		<u> </u>	<u> </u>
		25,696	267,278
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		(1,013)	(15,953)
		<u> </u>	<u> </u>
Other comprehensive income for the year		<u>24,683</u>	<u>251,325</u>
Total comprehensive expense for the year		<u>(159,687)</u>	<u>(238,456)</u>
Loss for the year attributable to:			
Owners of the Company		(174,829)	(484,312)
Non-controlling interests		(9,541)	(5,469)
		<u> </u>	<u> </u>
		<u>(184,370)</u>	<u>(489,781)</u>
Total comprehensive expense for the year attributable to:			
Owners of the Company		(150,146)	(232,987)
Non-controlling interests		(9,541)	(5,469)
		<u> </u>	<u> </u>
		<u>(159,687)</u>	<u>(238,456)</u>
Loss per share	8		
– Basic and diluted (RMB)		(0.24)	(0.67)
		<u> </u>	<u> </u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AT DECEMBER 31, 2023

		At December 31,	
		2023	2022
	<i>NOTES</i>	RMB'000	RMB'000
Non-current assets			
Property, plant and equipment		2,117	7,345
Right-of-use assets		3,492	12,177
Intangible assets		267,420	146,887
Financial assets at fair value through profit or loss		134,560	139,794
Equity instrument at FVTOCI		7,884	6,234
Rental deposits	10	—	2,513
		<u>415,473</u>	<u>314,950</u>
Current assets			
Deposits, prepayments and other receivables	10	121,388	77,640
Restricted bank deposits		729	1,875
Time deposits with original maturity over three months		2,171,011	1,806,812
Cash and cash equivalents		489,650	1,190,572
		<u>2,782,778</u>	<u>3,076,899</u>
Current liabilities			
Other payables	11	72,081	164,937
Lease liabilities		3,156	9,500
Deferred income		50,632	54,676
		<u>125,869</u>	<u>229,113</u>
Net current assets		<u>2,656,909</u>	<u>2,847,786</u>
Total assets less current liabilities		<u>3,072,382</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>3,072,382</u>	<u>3,157,497</u>
Capital and reserves			
Share capital		24	24
Share premium and reserves		3,119,016	3,194,590
Equity attributable to owners of the Company		3,119,040	3,194,614
Non-controlling interests		(46,658)	(37,117)
Total equity		<u>3,072,382</u>	<u>3,157,497</u>

NOTES TO THESE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 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 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 and Australia is United States Dollars (“**US\$**”) and Australian Dollars, respectively. The functional currency of the PRC operating subsidiaries is Renminbi (“**RMB**”). 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 INTERNATIONAL FINANCIAL REPORTING STANDARDS (“**IFRSs**”)

New and amendments to IFRSs that are mandatorily effective for the current year

In the current year, the Group has applied the following new and amendments to IFRSs 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, 2023 for the preparation of these 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
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies

Except as described below, the application of these new and amendments to IFRSs 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.

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

The Group has applied the amendments for the first time in the current year. The amendments narrow the scope of the recognition exemption of deferred tax liabilities and deferred tax assets in paragraphs 15 and 24 of IAS 12 *Income Taxes* (“**IAS 12**”) so that it no longer applies to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences.

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.

The application of the amendments has had no material impact on the Group's financial position and performance, except that the Group recognised deferred tax assets and deferred tax liabilities of RMB3,044,000 on a gross basis but it has no impact on the retained earnings at the earliest period presented.

2.2 Impacts on application of Amendments to IAS 12 Income Taxes International Tax Reform – Pillar Two model Rules

The Group has applied the amendments for the first time in the current year. IAS 12 is amended to add the exception to recognising and disclosing information about deferred tax assets and liabilities that are related to tax law enacted or substantively enacted to implement the Pillar Two model rules published by the Organisation for Economic Co-operation and Development (the “**Pillar Two legislation**”). The amendments require that entities apply the amendments immediately upon issuance and retrospectively. The amendments also require that entities to disclose separately its current tax expense/income related to Pillar Two income taxes in periods which the Pillar Two legislation is in effect, and the qualitative and quantitative information about its exposure to Pillar Two income taxes in periods in which the Pillar Two legislation is enacted or substantially enacted but not yet in effect in annual reporting periods beginning on or after January 1, 2023.

The Group is yet to apply the temporary exception during the current year because the Group's entities are operating in jurisdictions which the Pillar Two legislation has not yet been enacted or substantially enacted. The Group will disclose known or reasonably estimable information that helps users of financial statements to understand the Group's exposure to Pillar Two income taxes in the Group's annual consolidated financial statements when the Pillar Two legislation is enacted or substantially enacted and will disclose separately current tax expense/income related to Pillar Two income taxes when it is in effect.

2.3 Impacts on application of Amendments to IAS 1 and IFRS Practice Statement 2 Disclosure of Accounting Policies

The Group has applied the amendments for the first time in the current year. IAS 1 *Presentation of Financial Statements* is amended to replace all instances of the term “significant accounting policies” with “material accounting policy information”. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements.

The amendments also clarify that accounting policy information may be material because of the nature of the related transactions, other events or conditions, even if the amounts are immaterial. However, not all accounting policy information relating to material transactions, other events or conditions is itself material. If an entity chooses to disclose immaterial accounting policy information, such information must not obscure material accounting policy information.

IFRS Practice Statement 2 *Making Materiality Judgments* (the “**Practice Statement**”) is also amended to illustrate how an entity applies the “four-step materiality process” to accounting policy disclosures and to judge whether information about an accounting policy is material to its financial statements. Guidance and examples are added to the Practice Statement.

The application of the amendments has had no material impact on the Group’s financial positions and performance but has affected the disclosure of the Group’s accounting policies set out in these consolidated financial statements.

Amendments to IFRSs in issue but not yet effective

The Group has not early applied the following amendments to IFRSs that have been issued but are not yet effective:

Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ¹
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback ²
Amendments to IAS 1	Classification of Liabilities as Current or Non-current ²
Amendments to IAS 1	Non-current Liabilities with Covenants ²
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangement ²
Amendments to IAS 21	Lack of Exchangeability ³

¹ Effective for annual periods beginning on or after a date to be determined

² Effective for annual periods beginning on or after January 1, 2024

³ Effective for annual periods beginning on or after January 1, 2025

The directors of the Company anticipate that the application of all these amendments to IFRSs will have no material impact on these consolidated financial statements in the foreseeable future.

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

As at December 31, 2023, the Group has total non-current assets (excluding financial instruments) of RMB273.0 million (2022: RMB169.0 million), among which, RMB191.2 million (2022: RMB139.3 million), RMB75.8 million (2022: nil) and RMB6.0 million (2022: RMB29.7 million) were located in Cayman Islands, the USA and the PRC, respectively.

During the Reporting Period, all of the Group’s revenue from external customers were located in the PRC.

4. REVENUE

In the current year, the Group derives its revenue from the sale of pharmaceutical products amounted to RMB617,000 (2022: RMB51,626,000). 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. Following delivery, the customers have the discretion over the distribution and price to sell the goods and bear the risks of obsolescence and loss in relation to the goods. Payment of the transaction price is due immediately at the point the goods are delivered and transferred to the customer.

5. OTHER INCOME

	Year ended December 31,	
	2023	2022
	RMB’000	RMB’000
Bank interest income	108,023	37,204
Government grants (<i>note</i>)	55,274	70,310
Others	431	343
	<u>163,728</u>	<u>107,857</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 year, the Group received RMB50.0 million government grants (2022: RMB67.1 million). At December 31, 2023, government grants of RMB50.6 million (2022: RMB56.8 million) are recorded as deferred income and will be amortised upon compliance with the relevant conditions.

6. LOSS BEFORE TAX

	Year ended December 31,	
	2023	2022
	RMB'000	RMB'000
Loss before tax for the year has been arrived at after charging:		
Depreciation of property, plant and equipment	5,228	5,228
Depreciation of right-of-use assets	8,685	8,685
Amortisation of intangible assets (included in research and development expenses)	1,761	3,119
Auditors' remuneration	1,906	1,896
	<u>1,906</u>	<u>1,896</u>

7. INCOME TAX EXPENSE

The Company is incorporated in the Cayman Islands and has no assessable profits for both years.

Brii Bioscience, 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.

8. 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,	
	2023	2022
Loss for the year attributable to owners of the Company for the purpose of basic and diluted loss per share (RMB'000)	<u>(174,829)</u>	<u>(484,312)</u>
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share ('000)	<u>728,100</u>	<u>723,478</u>

For the years ended December 31, 2022 and 2023, the weighted average number of ordinary shares for the purpose of basic and diluted loss per share excluded the unvested restricted share units of the Company.

The computation of diluted loss per share for the years ended December 31, 2022 and 2023 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.

9. DIVIDENDS

No dividend was paid or declared by the Company during the years ended December 31, 2022 and 2023, nor has any dividend been proposed subsequent to the end of the reporting period.

10. RENTAL DEPOSITS/DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	At December 31,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments	47,685	19,589
Rental and other deposits	2,613	2,842
Value-added tax recoverable	53,607	46,172
Interests receivable	9,850	8,785
Other receivables	7,633	2,765
	<u>121,388</u>	<u>80,153</u>
Analysed as:		
Non-current	–	2,513
Current	<u>121,388</u>	<u>77,640</u>
	<u>121,388</u>	<u>80,153</u>

11. OTHER PAYABLES

	At December 31,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Payables for research and development expenses	20,539	113,531
Other payables for		
– legal and professional fee	1,901	2,225
– others	1,436	1,059
Other tax payables	2,011	1,861
Payroll payables	34,696	31,721
Accrued research and development expenses	11,498	3,397
Accrued issue costs	–	11,143
	<u>72,081</u>	<u>164,937</u>

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 December 31,	
	2023	2022
	RMB'000	RMB'000
0-30 days	15,186	12,285
31-60 days	4,059	5,883
61-90 days	1,125	2,958
Over 90 days	169	92,405
	20,539	113,531

12. EVENT AFTER THE REPORTING PERIOD

On February 14, 2024 (Hong Kong time), the Group and the VBI Parties agreed to enter into the following transactions: (i) the BRII-179 Acquisition, pursuant to which VBI and VBI Cda agree to sell, and the Company agrees to purchase, all the rights, title and interest, throughout the world in perpetuity, in and to any intellectual property related to BRII-179; (ii) the Technology Transfer, pursuant to which VBI will use commercially reasonable efforts to complete the Essential Activities in relation to the delivery of certain clinical materials of BRII-179 and to the transfer of certain materials and manufacturing responsibility for BRII-179 and PreHevbri™ to the Group; (iii) the VBI-1901 License, pursuant to which the Company agrees to acquire from VBI Cda an exclusive, sublicensable, royalty free, fully paid-up, perpetual, and irrevocable license to VBI-1901 for the development and commercialization in the Asia-Pacific region (excluding Japan), subject to satisfaction of certain conditions; and (iv) the Rehovot Assets Acquisition, pursuant to which SciVac agrees to sell, and the Group agrees to acquire and assume certain assets and liabilities related to the Rehovot Facility, subject to satisfaction of certain conditions, and the Group agrees to grant SciVac the Repurchase Right to repurchase certain assets related to the Rehovot Facility. In addition, as consideration for the BRII-179 Acquisition, the Technology Transfer and the VBI-1901 License, the Group will issue the Promissory Notes which are secured by the Collateral pursuant to the Collateral Agreements.

For details and the capitalized terms used in the above paragraph, please refer to the announcement of the Company dated February 14, 2024. Up to the date of issuance of these consolidated financial statements, the directors of the Company are still in the process of assessing the financial impact resulting from these transactions.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

Since our inception, we have pursued breakthrough scientific innovation to tackle major public health challenges, driven by critical patient insights. The exceptional leadership skills and industry expertise of our senior executives drive the execution of our portfolio development strategy. With a focused commitment to infectious disease, particularly HBV, where we hold significant competitive advantages and a robust portfolio of assets entering late-stage development, we are actively advancing our programs. Our cross-border organic operations also offer accelerated commercialization opportunities, leveraging our presence in both China and the U.S., we aim to improve the health of patients around the world.

Our strategic emphasis is on our HBV functional curative therapy program, where we see an opportunity to make a significant therapeutic impact on patients in China and worldwide. In collaboration with Vir, we are progressing multiple ongoing studies towards late-stage development, including BRII-179 and PEG-IFN α combination, elebsiran and PEG-IFN α combination (including a cohort with BRII-179 experienced patients), elebsiran and tobevibart with or without PEG-IFN α . We plan to initiate additional combination studies in the second half of 2024 to investigate the potential of BRII-179's role in enhancing HBV functional cure rate in combination with other modalities. Our goal is to enhance functional cure rate for the potential 'pro-responder' patients while avoiding ineffective treatments.

As our HBV programs transition to late-stage development, we are simultaneously curating a global manufacturing strategy for BRII-179 to ensure the timely integration of our R&D and manufacturing capabilities. This initiative was significantly bolstered by the recent transactions of the Company entered with VBI, VBI Cda and SciVac to secure full intellectual property rights for BRII-179 and eliminate all future payment obligations of the Company to VBI with respect to BRII-179/PreHevbri™ under the previous collaboration agreements entered into between the parties. Additionally, steps were taken to enhance manufacturing capabilities by acquiring technology transfer and facilities in Rehovot for BRII-179/PreHevbri™. These efforts are aligned to support the advancement of our potential paradigm shifting HBV program as well as to expand our future supply capacity and internal manufacturing capabilities.

2023 was an important year for the Company, with key insights received from multiple Phase 2 combination studies. Through vigorous clinical investigations over the past five years, the Company has gathered essential understanding about what is important to sustain the loss of HBsAg. On the ground of above, we have developed a strategy to assess and enhance HBV patients' intrinsic immunity, enriching patients who may have the best chance of achieving a cure while sparing others from poorly tolerated regimens. These pivotal breakthroughs inform our late-stage clinical combination trials.

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 program is centered around HBV functional cure, primarily in China.

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/BLA	Commercial	Our Rights	Partners	
Infectious Disease Programs											
Hepatitis B	Treatment ⁽¹⁾	BRII-179	[Progress bar: Pre-clinical to Phase 2]							Global	VBI
		BRII-835 (Elebsiran) ⁽²⁾	[Progress bar: Pre-clinical to Phase 2]							Greater China*	VIR
		BRII-877 (Tobevibart) ⁽³⁾	[Progress bar: Pre-clinical to Phase 2]							Greater China*	VIR
	Prevention	PreHevbri ^{TM(4)}	[Progress bar: Pre-clinical to Phase 3]							APAC ex-Japan ⁽⁵⁾	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) ⁽⁵⁾	[Progress bar: Pre-clinical to Phase 2]							Greater China*	AN ² Therapeutics
Central Nervous System Disease Programs											
PPD		BRII-296	[Progress bar: Pre-clinical to Phase 2]							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

Source: Company information

Notes:

- (1) The Phase 2 combination clinical trials conducted by Brie Bio:
 - BRII-179/PEG-IFN α
 - BRII-179/BRII-835
 - BRII-835/PEG-IFN α
- (2) Elebsiran was previously known as VIR-2218.
- (3) Tobevibart was previously known as VIR-3434. The Phase 2 clinical trials have been conducted by VIR.
- (4) VBI launched PreHevbriTM/PreHevbrio[®] in the United States, Canada, European Union, European Economic Area, the United Kingdom, and Israel. Brie Bio acquired exclusive rights for APAC countries (ex-Japan) in July 2023.
- (5) 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. In addition to progressing multiple clinical trials and hosting R&D Day, we presented datasets at medical conferences that provided valuable insights into improving the functional cure rate for HBV patients and identifying patients most likely to respond to curative treatments.

With our important HBV candidates transition to late-stage clinical development, we have strategically shifted our resources to focus more heavily on our HBV program, including initiating a global manufacturing strategy to align our R&D capabilities with manufacturing resources. As such, we are actively seeking partners for the continued development of our promising MDR/XDR, HIV, and CNS programs.

Our key achievements as of the date of this announcement, along with 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 and partners, Vir and VBI, the Company is progressing multiple combination studies for the treatment of HBV to improve 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 87 million people impacted by this disease, yet there is no effective functional cure currently available for 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.

- BRII-179 received Breakthrough Therapy Designation from the CDE in November 2023, expediting innovative treatments for HBV patients.
- In November 2023, the Company presented two late-breaking posters on BRII-179 at the AASLD The Liver Meeting®, showing an important connection between HBsAg loss and anti-HBs antibody response. These data enable a clear direction in further improving the functional cure rate and identifying patients likely to respond to curative treatments.
 - BRII-179 induced functional immune responses that improve the rate and duration of HBsAg loss in CHB patients who receive PEG-IFN α treatment, thereby increasing the CHB functional cure rate.
 - Translational research data from Bii Bio's Phase 1b/2a studies on BRII-179 and BRII-179 in combination with elebsiran suggest that BRII-179 may offer a unique opportunity to identify CHB patients who are able to elicit the necessary HBV-specific immune responses hence achieving a higher functional cure rate in the selected patients while sparing others from unnecessary treatments.

- The Company plans to initiate additional combination studies in the second half of 2024 to confirm the ability of BRII-179 to enhance HBV functional cure rate in combination with other modalities.
- We will present data on patients meeting NRTI discontinuation criteria from its ongoing Phase 2 study of BRII-179 in combination with PEG-IFN α in CHB patients as an oral late-breaking presentation at the 33rd Conference of Asian Pacific Association for the Study of the Liver, to be held from March 27 to 31, 2024 in Kyoto, Japan.

Elebsiran and Tobeivart Related Studies and Plans

Elebsiran (also known as BRII-835 or VIR-2218) is a N-Acetylgalactosamine-conjugated siRNA targeting all HBV viral RNAs that has shown to block viral transcription, reduce viral proteins and alleviate immune suppression.

Tobeivart (also known as BRII-877 or 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. Tobeivart, 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.

- Completed enrollment in the Phase 2 study of elebsiran in combination with PEG-IFN α in the APAC regions including mainland China. The primary objectives of this study are to gain deeper insights into the contribution of elebsiran towards improving HBV cure rate relative to PEG-IFN α alone and to explore the role of BRII-179 in enriching patients to achieve better curative outcomes. Early topline result is expected in the fourth quarter of 2024.
- In November 2023, our development partner, Vir, presented new MARCH Part B data at the AASLD The Liver Meeting. The data demonstrated an approximately three-fold higher response rate when adding tobeivart to a regimen of elebsiran with or without PEG-IFN α after 24 weeks of treatment (15.0% for tobeivart + elebsiran + PEG-IFN α and 14.3% for tobeivart + elebsiran). The data from cohorts undergoing 48 weeks of treatment will be available in the fourth quarter of 2024.
- In another late-breaker presentation at the AASLD The Liver Meeting, with an update at the 42nd Annual J.P. Morgan Healthcare Conference in January 2024, Vir shared initial SOLISTICE data from a small subset of chronic hepatitis delta participants. After 12 weeks of combination treatment with tobeivart and elebsiran, 5 of 6 participants achieved undetectable HDV RNA and 6 out of 6 were below the lower limit of quantitation. Additional data will be presented in the second quarter of 2024 and complete 24-week treatment data are expected in the fourth quarter of 2024.
- A Phase 1 study of tobeivart is ongoing in China. Human PK in mainland Chinese subjects will be compared to subjects from other APAC regions and Europe.

PreHevbri™ Related Updates and Plans

PreHevbri™ is a differentiated 3-antigen adult HBV prophylactic vaccine. It is currently approved for adult use under the brand name PreHevbrio® 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 July 2023, the Company secured exclusive development and commercialization rights for PreHevbri™ in Greater China and certain other Asia Pacific regions (excluding Japan) and has submitted two pre-INDs to the CDE for PreHevbri™'s registration plan in China. A Market Authorization Application has also been filed in Hong Kong. Currently, the Company is actively seeking partnership for the commercialization of PreHevbri™.

Additional Clinical and Pre-Clinical Development Updates

Based on the Company's strategy to focus on its advanced HBV programs, the Company is pursuing partnership opportunities for the continued development of these programs.

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.

The U.S. FDA has designated BRII-693 to be a QIDP, 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.

- In June 2023, we gained exclusive global rights to develop and commercialize BRII-693, a novel polymyxin for the treatment of serious gram-negative infections. The Company is seeking strategic funding partners to expedite the development of BRII-693, a novel antibiotic intended to help tackle the growing worldwide threat of antimicrobial resistance.
- In April 2023, we submitted a pre-IND to the NMPA of China for the development of BRII-693 with plans to initiate one Phase 1 PK bridging study in China. Additional clinical PK studies to enable the initiation of a Phase 3 trial are in planning. These studies are crucial to support global development efforts. A large, global Phase 3 registrational trial in hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia, is expected to begin in 2025.

HIV Infection Program

BRII-753 is an internally discovered NCE currently in the preclinical stage of development. BRII-753 is being developed as a long-acting subcutaneous injection with potential for dosing once monthly, once quarterly, or twice yearly, and 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.

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.

- 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

BRII-658 (Epetraborole) 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.

- In February 2024, our partner, AN2, announced a voluntary pause of its Phase 3 enrollment in a Phase 2/3 clinical trial for epetraborole for the treatment-refractory *Mycobacterium avium* complex lung disease, pending further data review.

Postpartum Depression and Major Depressive Disorders Program

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.

- In September 2023, the first patient was dosed in the Phase 2 study evaluating BRII-296, a LAI therapy in development for the treatment of PPD. The Company expects data readouts from the Phase 2 trial by the second quarter of 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.

- Dosing has been completed in a Phase 1 clinical trial for BRII-297, a LAI being developed to treat anxiety and depressive disorders. The study aims to evaluate the safety, tolerability, and pharmacokinetics of BRII-297 in healthy volunteers with data expected by the second half of 2024.

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

- The Company has appointed Dr. Brian A. Johns as Chief Scientific Officer to oversee its discovery programs and shape the Company's future pipeline strategy. Our new organizational strategy is underpinned by highly experienced leaders in infectious diseases who are committed to clear deliverables across the Company's pipeline.
- The Company continues to receive broad industry recognition for its corporate and clinical development accomplishments, including "2023 PharmaVoice 100 Top Industry Leaders" by PharmaVoice, "Most Promising Hong Kong Listed Pharmaceutical Companies" by Sina Finance, and maintained an "A" rating from the MSCI ESG Rating.

Research and 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. We prioritize diseases based on patients' needs, aiming to provide viable solutions to prevalent infectious diseases and central systems disorder diseases. Leveraging our team primarily located in China and partnerships in the U.S., we expedite clinical development more swiftly in China, or participate in late-stage global studies, driven by our shared vision of delivering world-class medicines.

Our R&D capabilities, both in-house and through collaborations, enable us to source innovative therapies for China and globally. 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, CROs, CMOs, CDMOs and research institutions. With cross-border organic operations as a competitive advantage, we plan to further enhance our capacity and 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; Chief Scientific Officer Dr. Brian A. Johns; and Head of China R&D Dr. Qing Zhu. Guided by our esteemed Board and scientific advisory board members, who possess diverse industry expertise and a track record of successful drug development, our R&D process and candidate selection are driven by leading experts across multiple disciplines.

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 RMB402.7 million for the year ended December 31, 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

Our pipeline includes therapeutic candidates with a mix of in-licensed Greater China rights and global rights.

As of the date of this announcement, our efforts have primarily focused on building our therapeutic candidate pipeline. Most of our programs are in various stages of clinical development and we do not anticipate sales or commercialization of other drug candidates in the immediate future. For PreHevbri™, we are seeking partnerships for commercialization in APAC regions. As our pipeline gradually matures, we will evaluate strategic commercialization options, ensuring that we maximize their potential to address critical unmet needs.

FUTURE DEVELOPMENT

Carrying on with our corporate strategy of devoting to alleviating public health burden and improving patients' experience through developing innovative treatment options, the Company strives to further advance our diverse pipelines by leveraging our in-house capabilities and exploring external partnership.

As a leading company in HBV functional cure area, we will keep focusing on increasing the functional cure rate through different combination treatments. Together with our partner Vir, we will further evaluate our combination treatment regimens under development for a higher functional cure rate for HBV infection leveraging the additional data available from several ongoing trials, and plan to initiate definitive clinical studies to bring a combination treatment regimen to the next stage of development in the Greater China. On the other hand, given that our research candidates are approaching late-stage development, we have considered to establish a cost-effective manufacturing and supply chain management plan, starting with the technology transfer of BRII-179.

For our other programs, we are seeking partnerships for continued development of our current CNS candidates, HIV program and commercialize PreHevbri™ in China and other Asia Pacific regions.

For a long run, we will keep expanding 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. As the Company has stepped into its second five-year period, we redirect our discovery strategy with greater focus on platforms and disease areas consistent with the long-term pipeline interest, priority and strategy of the Company. To support sustainable long-term development, we will continue to optimize our organization to deliver innovation and support our business development aligned with our mission to tackle the world's biggest challenges in public health.

SUBSEQUENT EVENTS

Enter into Several Agreements with VBI

On February 14, 2024 (Hong Kong time), the Group and the VBI Parties agreed to enter into the following transactions: (i) the BRII-179 Acquisition, pursuant to which VBI and VBI Cda agree to sell, and the Company agrees to purchase, all the rights, title and interest, throughout the world in perpetuity, in and to any intellectual property related to BRII-179; (ii) the Technology Transfer, pursuant to which VBI will use commercially reasonable efforts to complete the Essential Activities in relation to the delivery of certain clinical materials of BRII-179 and to the transfer of certain materials and manufacturing responsibility for BRII-179 and PreHevbri™ to the Group; (iii) the VBI-1901 License, pursuant to which the Company agrees to acquire from VBI Cda an exclusive, sublicensable, royalty free, fully paid-up, perpetual, and irrevocable license to VBI-1901 for the development and commercialization in the Asia-Pacific region (excluding Japan), subject to satisfaction of certain conditions; and (iv) the Rehovot Assets Acquisition, pursuant to which SciVac agrees to sell, and the Group agrees to acquire and assume certain assets and liabilities related to the Rehovot Facility, subject to satisfaction of certain conditions, and the Group agrees to grant SciVac the Repurchase Right to repurchase certain assets related to the Rehovot Facility. In addition, as consideration for the BRII-179 Acquisition, the Technology Transfer and the VBI-1901 License, the Group will issue the Promissory Notes which are secured by the Collateral pursuant to the Collateral Agreements.

For details and the capitalized terms used in the above paragraph, please refer to the announcement of the Company dated February 14, 2024.

FINANCIAL REVIEW

1. Revenue

Our revenue was decreased by RMB51.0 million from RMB51.6 million for the year ended December 31, 2022 to RMB0.6 million for the year ended December 31, 2023 due to the discontinuation of COVID-19 programs.

2. Other income

	Year ended December 31,	
	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Bank interest income	108,023	37,204
Government grants	55,274	70,310
Others	431	343
Total	<u>163,728</u>	<u>107,857</u>

Our other income was increased by RMB55.8 million from RMB107.9 million for the year ended December 31, 2022 to RMB163.7 million for the year ended December 31, 2023. This was mainly due to the increased bank interest income of RMB70.8 million attributable to the rising interest rates on USD and HKD time deposits. The increase of bank interest income was partially offset by the decrease of government grants income of RMB15.0 million. These grants mainly represent the incentive and other subsidies from the PRC government which are for R&D activities and are recognized upon compliance with the attached conditions.

3. Other gains and losses

Our other gains and losses were increased by RMB264.7 million from losses of RMB12.3 million for the year ended December 31, 2022 to gains of RMB252.4 million for the year ended December 31, 2023. The increase was primarily attributable to the fair value gain on financial assets and the acquired intangible asset.

4. Fair value loss on equity instruments at FVTOCI

Our fair value loss on equity instruments at FVTOCI was decreased by RMB10.5 million from loss of RMB30.1 million for the year ended December 31, 2022 to loss of RMB19.6 million for the year ended December 31, 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

	Year ended December 31,	
	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Third-party contracting cost	218,363	253,020
Employee cost	174,815	169,544
Licensing fees	–	6,728
Amortization	1,358	2,745
Others	8,169	8,597
Total	<u>402,705</u>	<u>440,634</u>

Our research and development expenses were decreased by RMB37.9 million from RMB440.6 million for the year ended December 31, 2022 to RMB402.7 million for the year ended December 31, 2023. The decrease was primarily attributable to the decrease in third-party contracting cost of RMB34.6 million mainly relating to COVID-19 programs. The decrease was partially offset by the increase in employee cost by RMB5.3 million mainly due to the increase in average headcount of research and development personnel to further enhance our in-house research and development capabilities during the year.

6. Administrative expenses

	Year ended December 31,	
	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Employee cost	126,498	100,849
Professional fees	27,117	33,490
Depreciation and amortization	14,316	14,315
Office expenses	4,489	2,992
Others	24,079	16,983
Total	<u>196,499</u>	<u>168,629</u>

Our administrative expenses were increased by RMB27.9 million from RMB168.6 million for the year ended December 31, 2022 to RMB196.5 million for the year ended December 31, 2023. This was primarily attributable to the employee cost increased by RMB25.7 million from RMB100.8 million for the year ended December 31, 2022 to RMB126.5 million for the year ended December 31, 2023, which was primarily attributable to the increase in average employee headcount in 2023 and one-off reversal in share-based compensation cost in 2022. In addition, the other expenses increased by RMB7.1 million were mainly due to the increased IT expense for software license.

7. Liquidity and Capital resources

As of December 31, 2023, our bank and cash balances, including restricted bank deposits and time deposits, decreased to RMB2,661.4 million from RMB2,999.3 million as of December 31, 2022. The decrease was 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 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 non-cash items and one-time events, 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 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 years indicated:

	Year ended December 31,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Loss for the year	(184,370)	(489,781)
Added:		
Share-based compensation	<u>64,223</u>	<u>77,928</u>
Adjusted loss for the year	<u><u>(120,147)</u></u>	<u><u>(411,853)</u></u>

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,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Research and development expenses for the year	(402,705)	(440,634)
Added:		
Share-based compensation	<u>29,756</u>	<u>44,245</u>
Adjusted research and development expenses for the year	<u><u>(372,949)</u></u>	<u><u>(396,389)</u></u>

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

	Year ended December 31,	
	2023	2022
	RMB'000	RMB'000
Administrative expenses for the year	(196,499)	(168,629)
Added:		
Share-based compensation	<u>37,306</u>	<u>25,448</u>
Adjusted administrative expenses for the year	<u>(159,193)</u>	<u>(143,181)</u>

9. Key financial ratios

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

	As at December 31, 2023	As at December 31, 2022
Current ratio ⁽¹⁾	2,211%	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 December 31, 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 December 31, 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 three to five years. As at December 31, 2023, the Group had lease liabilities of RMB3.2 million recognized under IFRS 16.

11. Significant investments, material acquisitions and disposals

As at December 31, 2023, the Group did not hold any significant investments. For the year ended December 31, 2023, the Group did not have material acquisitions or disposals of subsidiaries, associates, and joint ventures.

12. Charge on the Group's assets

As at December 31, 2023, none of the Group's assets were charged with any parties or financial institutions (as at 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 December 31, 2023, the Group's restricted bank deposits, time deposits with original maturity over three months and bank balances and cash were denominated as to 37.9% in US dollars, 42.9% in Hong Kong dollars, and 19.2% in RMB.

14. Employees and remuneration

As at December 31, 2023, we had a total of 128 employees. The following table sets forth the total number of employees by function as of December 31, 2023:

Function	Number of employees	% of total
Research and development	91	71%
Administration	37	29%
Total	<u>128</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 year ended December 31, 2023 was RMB302 million, as compared to RMB294 million for the year ended December 31, 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 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).

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 December 31, 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 December 31, 2023 (HK\$ million)	Unutilized amount as at December 31, 2023 (HK\$ million)
Used for our HBV functional cure programs	38%	994.1	686.8	192.0	499.3	494.8
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	192.0	499.3	338.0
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	41.1	146.4	29.6
Used for our MDR/XDR gram-negative infections programs	11%	294.0	259.9	18.8	52.9	241.1
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	18.8	44.4	190.1
Used for regulatory milestone payments for BRII-636, BRII-672 and BRII-693	2%	59.5	51.0	–	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	120.5	236.5	259.8
Used for discovery and business development activities for pipeline expansion	15%	392.0	334.8	16.8	74.0	318.0
Used for working capital and general corporate purposes	10%	261.4	57.2	57.2	261.4	–
Total	100%	2,613.8	1,789.7	446.4	1,270.5	1,343.3

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 2026.

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, 2023.

CLOSURE OF THE REGISTER OF MEMBERS

The Company will hold the AGM on Tuesday, June 25, 2024. The register of members of the Company will be closed from Thursday, June 20, 2024 to Tuesday, June 25, 2024, 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 19, 2024.

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 (formerly known as 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 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, 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 C3 (formerly known as 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.

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 condensed consolidated financial statements of the Group for the year ended December 31, 2023), and is of the view that the annual results of the Group for the year ended December 31, 2023 is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

SCOPE OF WORK OF 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, 2023 as set out in this announcement have been agreed by the Group’s auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the Group’s audited consolidated financial statements for the year as approved by the Board on March 22, 2024. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement in accordance with International Standards on Auditing, International Standards on Review Engagements or International Standards on Assurance Engagements issued by the International Auditing and Assurance Standards Board and consequently no assurance 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, 2023, and certain assumptions with respect to the characterization of our income and assets as active or passive, we expect the Company to be classified as a PFIC for our taxable year ending December 31, 2023. 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.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our Shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the Shares, regardless of whether we continue to meet the asset test unless (i) we cease to be a PFIC and the U.S. Holder has made a “deemed sale” election under the PFIC rules, or (ii) the U.S. Holder makes a Qualified Electing Fund election (“**QEF Election**”) or is eligible to make and makes a mark-to-market election (as described below), with respect to all taxable years during such U.S. Holder’s holding period in which we are a PFIC. If the “deemed sale” election is made, a U.S. Holder will be deemed to have sold the Shares the U.S. Holder holds at their fair market value as of the date of such deemed sale and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder’s Shares with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any “excess distribution” the U.S. Holder receives from us or any gain from an actual sale or other disposition of the Shares. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if such election becomes available.

For each taxable year we are treated as a PFIC with respect to U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any “excess distribution” such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including a pledge) of our Shares, unless (i) such U.S. Holder makes a QEF Election or (ii) our Shares constitute “marketable” securities, and such U.S. Holder makes a mark-to-market election as discussed below. Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder’s holding period for the Shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder’s holding period for the Shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the Shares cannot be treated as capital gains, even if a U.S. Holder holds the Shares as capital assets. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to qualified dividends.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to our Shares by making a mark-to-market election with respect to the Shares, provided that the Shares are “marketable.” Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the Shares.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of our Shares at the close of the taxable year over the U.S. Holder’s adjusted tax basis in the Shares. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder’s adjusted basis in the Shares over the fair market value of the Shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the Shares will be treated as ordinary income, and any losses incurred on a sale or other disposition of the Shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the U.S. IRS unless the Shares cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves “marketable.” As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our Shares, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Alternatively, a U.S. Holder can make an election, if we provide the necessary information, to treat us and each lower-tier PFIC as a qualified electing fund, or a QEF Election, in the first taxable year we (and our relevant subsidiaries) are treated as a PFIC with respect to the U.S. Holder. If such election remains in place while we and any lower-tier PFIC subsidiaries are PFICs, we and our subsidiaries will not be treated as PFICs with respect to such U.S. Holder. A U.S. Holder must make the QEF Election for us and for each of our subsidiaries that is a PFIC by attaching a separate properly completed U.S. IRS Form 8621 for each such PFIC to the U.S. Holder’s timely filed U.S. federal income tax return. If we are a PFIC for our taxable year ending December 31, 2023, or any subsequent taxable year, we expect to provide U.S. Holders, a “PFIC Annual Information Statement”, with the information required to allow U.S. Holders to make a QEF Election for U.S. federal income tax purposes.

If a U.S. Holder makes a QEF Election with respect to a PFIC, then in lieu of the tax consequences described above, the U.S. Holder will be currently taxable on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC. If a U.S. Holder makes a QEF Election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder's income under the QEF Election would not be taxable to the holder. A U.S. Holder will increase its tax basis in its shares by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on the shares that is not included in the holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of shares in an amount equal to the difference between the amount realized and the holder's adjusted tax basis in the shares. U.S. Holders should note that if they make QEF Elections with respect to us and lower-tier PFICs, they may be required to pay U.S. federal income tax with respect to their Shares for any taxable year significantly in excess of any cash distributions (which may be zero) received on the Shares for such taxable year. U.S. Holders should consult their tax advisors regarding making QEF Elections in their particular circumstances. If a U.S. Holder does not make and maintain a QEF election for the U.S. Holder's entire holding period for the Shares by making the election for the first year in which the U.S. Holder owns the Shares, the U.S. Holder will be subject to the adverse PFIC rules discussed above unless the U.S. Holder can properly make a 'purging election' with respect to the Shares in connection with the U.S. Holder's QEF Election. A purging election may require the U.S. Holder to recognize taxable gain on the U.S. Holder's Shares. No purging election is necessary for a U.S. Holder that timely makes a QEF election for the first year in which the U.S. Holder acquired our Shares.

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, 2023 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 25, 2024
“AIDS”	acquired immunodeficiency syndrome, defined as an HIV infection with either a CD4+ T-cell count below 200 cells per μ L or the occurrence of specific diseases associated with HIV infection
“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

“ART”	antiretroviral therapy
“Audit and Risk Committee”	the audit and risk committee of the Board
“BLA”	biologics license application
“Board”	the board of directors of the Company
“CD4+”	cluster of differentiation antigen 4
“CDE”	the Center for Drug Evaluation of the NMPA of China
“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 C1 (formerly known as Appendix 14) to the Listing Rules
“CHB”	chronic hepatitis B
“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 (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
“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
“EFdA”	an NRTTI and an investigational drug for the treatment of HIV infection
“ESG”	environmental, social and governance
“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 PRC 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 PRC
“HK\$” or “HKD”	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
“LAI”	long acting injection
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange
“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 (formerly known as 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
“NDA”	new drug application
“NMPA”	the National Medical Products Administration
“NRTI”	nucleotide/nucleoside reverse transcriptase inhibitors, a form of ART used to treat HIV infection or AIDS
“NRTTI”	nucleoside analogue reverse transcriptase translocation inhibitor
“NTM”	nontuberculous mycobacteria

“PEG-IFN α ”	pegylated interferon alfa
“PK”	pharmacokinetics
“PPD”	postpartum depression
“Prospectus”	the prospectus of the Company dated June 30, 2021
“QIDP”	Qualified Infectious Disease Product
“Reporting Period”	the year ended December 31, 2023
“RMB”	Renminbi, the lawful currency of the PRC
“RNA”	ribonucleic acid
“R&D”	research and development
“SciVac”	SciVac Ltd., a company incorporated under the laws of Israel, being a wholly-owned subsidiary of VBI
“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.”	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.

“U.S. IRS”	the Internal Revenue Service of U.S.
“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)
“VBI Cda”	Variation Biotechnologies Inc., a company incorporated under the laws of Canada, being an indirectly wholly-owned subsidiary of VBI
“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, March 22, 2024

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.