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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, 2022 AND CHANGE IN USE OF PROCEEDS

The Board of the Company is pleased to announce the consolidated annual results of the Group for the year ended December 31, 2022, together with the comparative figures for the previous year, which have been reviewed by the Audit and Risk Committee.

# FINANCIAL HIGHLIGHTS

- The revenue increased by RMB51.6 million from nil for the year ended December 31, 2022. The increase was mainly attributable to the commercialization of the long-acting amubarvimab/romlusevimab combination therapy in China for the treatment of COVID-19.
- Other income was RMB107.9 million for the year ended December 31, 2022, representing an increase of RMB8.9 million or 9.0%, compared with RMB99.0 million for the year ended December 31, 2021. The increase was mainly due to the increase in bank interest income of RMB30.7 million attributable to the increased bank and cash balances after the Global Offering. The increase was partially offset by the decrease in income recognized from PRC government grants.
- Research and development expenses were RMB440.6 million for the year ended December 31, 2022, representing a decrease of RMB54.0 million or 10.9%, compared with RMB494.6 million for the year ended December 31, 2021. The decrease was primarily due to the decrease in third party contracting costs relating to COVID-19 programs. It was partially offset by the increase in the employee costs for our continuous development in clinical trials.
- Administrative expenses were RMB168.6 million for the year ended December 31, 2022, representing a decrease of RMB39.8 million or 19.1%, compared with RMB208.4 million for the year ended December 31, 2021. The decrease was primarily attributable to the decrease in the employee costs.

• Total comprehensive expense for the year ended December 31, 2022, was RMB238.5 million, representing a decrease of RMB4,010.5 million or 94.4%, compared with RMB4,249.0 million for the year ended December 31, 2021. The decrease was primarily attributable to the decrease in fair value loss on financial liabilities at fair value through profit or loss.

# **BUSINESS HIGHLIGHTS**

We are a biotechnology company developing therapies to improve health in diseases where patients experience high unmet medical needs, limited choice and significant social stigmas. In particular, we specialize in infectious diseases and central nervous system diseases with a mission to tackle public health challenges through breakthrough scientific innovation and critical patient insights. In 2022, we heightened our focus on our two lead clinical programs, dedicated to developing a novel functional cure regimen for hepatitis B viral infection in China and potential first-of-its-kind treatments for postpartum depression and major depressive disorders in the U.S.

In support of our governance and business development strategy, and as our programs advance through clinical development, we expanded the depth and breadth of our senior executive leadership team and board structure to guide our public-health-inspired programs during the Reporting Period. Our international teams in China and the U.S. are committed to and adept at collaborating to maximize our collective strengths and various areas of expertise in both key markets, as well as other areas around the world. Together, our team is working to make a positive impact on underserved patient populations, public health and society, as we invest in medicines that have the potential to make a profound difference in many people's lives.

As of the date of this announcement, we had established a diverse pipeline with more than 10 product candidates. They are primarily under clinical development and rely on our in-house team, which has strong product discovery and translational research capabilities, as well as our extensive partnerships with industry leaders around the globe. In search of viable treatments, in China, we are primarily developing therapies to address HBV and multidrug resistant and extensively drug resistant gram-negative infections. We are advancing our programs in China through both in-house R&D and with our partners. We also have a commercially approved treatment for COVID-19 in China since July 2022. In the U.S., we are mainly focused on our anti-depression program, particularly PPD/MDD with plans to initiate additional indications later this year. We are also exploring partnership opportunities for the future development of our internally discovered HIV candidates in the U.S.

Driven by our unique combination therapy design based on RNA interference therapeutics, we aim to be the leading company to develop a novel functional cure regimen for HBV. China accounts for the world's largest population of HBV patients, where we have the world's most advanced clinical development program with a robust portfolio of HBV assets that we are evaluating primarily as combination therapies. We are leveraging our strategic partnerships to develop novel combination treatments to improve the probability of achieving a higher rate of functional cure for each subpopulation of HBV patients. As we work to bring a therapy through clinical development in China, our partner, Vir, is simultaneously conducting studies globally. By conducting multiple trials with varying therapeutic regimens, in combination with or without standard-of-care treatments, we maximize our chances of finding a functional cure for HBV at a faster pace.

In July 2022, we further strengthened our core HBV assets by exercising our option to in-license BRII-877 (VIR-3434), a strong HBV specific neutralizing monoclonal antibody from Vir, which we have the rights to develop and commercialize in Greater China.

During 2022, we continuously built-out our capabilities and expertise in CNS with internal talent, prioritizing our program for PPD/MDD treatment and other anxiety and depressive disorders. We are in preparation for a Phase 2 proof-of-concept trial with BRII-296 in PPD patients in the U.S. Anxiety and depressive disorders are our initial targets with BRII-297, which is preparing to enter a first-in-human Phase 1 study in Australia.

For our HIV portfolio, we are now exploring partnership opportunities to continue developing BRII-732 as part of a potential oral, once-weekly, long-acting combination treatment option for HIV patients, based on the PK data from a completed Phase 1 study presented at IDWeek in October 2022. We are also pleased to introduce a new candidate BRII-753 to our HIV portfolio and will further explore innovative long-term therapy for HIV patients.

Besides, we hold the rights in Greater China to therapeutic candidates for the treatment of multidrug resistant and extensively drug resistant gram-negative infections and nontuberculous mycobacteria, which are under clinical development by our partners Qpex and AN2, respectively.

In addition, the Company has made the decision to discontinue its amubarvimab/romlusevimab antibody combination program for COVID-19 and has stopped manufacturing efforts in order to redirect resources to high-priority programs. This determination is based on constantly evolving COVID-19 trends and policy updates, as well as protracted regulatory inspections at our CDMO sites.

As our innovation is driven by patient insight, we have made great efforts to engage in patient centric programs. These activities and industry acknowledgements strengthen our ability to foster productive relationships with patients, their caregivers, and the disease-specific non-profit groups that support them. We believe patient-centricity ensures patients' voices are well heard and understood across every function of the discovery and development process, from R&D through commercialization.

Highlighting our achievements as a rapidly advancing small biotech company, we were added to the MSCI China Small Cap Index in Hong Kong in 2022, which enhances our visibility and recognition by the global investor community.

Looking forward, we will leverage our recent success to advance the development of our portfolio to satisfy significant unmet medical needs and ease heavy public health burdens from a patient-centric vantage point.

# Major Milestones Achieved as of the Date of This Announcement

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

- BRII-179 (VBI-2601) in Combination with BRII-835 (VIR-2218) (Study conducted by Brii Bio)
  - o In February 2022, we completed the enrollment of 90 patients from the Asia-Pacific region in our Phase 2 MRCT combination study.

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

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

o In December 2022, the Company completed patient enrollment in part one of a Phase 2 combination trial evaluating the addition of BRII-179 (VBI-2601) in chronic HBV patients already receiving PEG-IFN-α and NRTI treatment.

# • VIR-2218 (BRII-835) in Combination with PEG-IFN-α (Study conducted by Vir)

- o Vir presented data at the International Liver Congress in June 2022, showing longer treatment duration of monthly VIR-2218 (BRII-835) results in deeper and more sustained reductions in HBsAg in participants with chronic HBV infection.
- o In November 2022, Vir announced end-of-treatment data from an ongoing Phase 2 trial of combination of VIR-2218 (BRII-835) with PEG-IFN- $\alpha$  (lasting for 48 weeks) at the AASLD 2022 meeting, which demonstrated that approximately 31% of patients with chronic HBV infection achieved HBsAg seroclearance with hepatitis B antibodies seroconversion with no new safety signals.

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

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In November 2022, Vir presented initial end-of-treatment data at AASLD's The Liver Meeting<sup>®</sup> from Part A of its ongoing Phase 2 MARCH study evaluating VIR-2218 (BRII-835) in combination with VIR-3434 (BRII-877) in participants with chronic HBV infection who received NRTI therapy. The data indicated additive HBsAg reductions from VIR-2218 (BRII-835) and VIR-3434 (BRII-877) with combination regimens achieving a much greater HBsAg reduction than either alone in all patients with no safety signals.

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

# • BRII-296

o In September 2022, we announced positive topline results from a Phase 1 study for BRII-296 with data demonstrating that a single administration of the investigational therapy at 600 mg delivered a favorable pharmacokinetic profile and was safe and well-tolerated in healthy subjects. Early feedback from physicians and patient communities has been very positive and reinforces the potential for a first-of-its-kind single-injection treatment option for PPD in the U.S.

# • BRII-297

• We have conducted IND-enabling studies with BRII-297 targeting various anxiety and depressive disorders.

# HIV Program (Internally discovered)

# • BRII-732

- o We completed our Phase 1 SAD/MAD study of BRII-732 in May 2022.
- o In October 2022, we presented positive Phase 1 data showing that BRII-732 demonstrated an acceptable safety and tolerability profile, as well as a favorable and linear PK profile that achieved therapeutic targets in healthy volunteers, reinforcing its potential as an oral once-weekly therapy for the treatment of HIV infections.
- o In December 2022, we were notified by the U.S. FDA that it had lifted the clinical hold on the Company's planned Phase 1 study to investigate a lower oral dose of once-weekly BRII-732. The Company is exploring partnership opportunities to continue developing BRII-732 as part of a potential oral, once-weekly, long-acting combination treatment option for HIV patients.

# **BRII-753**

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• We selected a new clinical candidate, BRII-753, as a long-acting subcutaneous injection therapy with the goal to extend the dosing schedule to once monthly, once quarterly or twice-yearly.

# **BRII-778**

- We completed the final clinical study report for our BRII-778 Phase 1 SAD/MAD trial in June 2022.
- o Based on the PK data from a completed Phase 1 study, which determined that additional development work was required to achieve optimal PK targets for the treatment of HIV, the Company has made the decision to discontinue the development of BRII-778.

# MDR/XDR Gram-negative Bacteria Infections Program (Licensed from Qpex)

# • BRII-693 (QPX-9003)

- Qpex announced in early 2022 that BRII-693 received QIDP designation by the U.S. FDA.
- o In October 2022, Qpex presented interim Phase 1 result at IDWeek from its completed first-in-human clinical study, demonstrating that BRII-693 was safe and well tolerated at all doses tested, and the result supports continued development of BRII-693 for the treatment of *Acinetobacter baumannii* and *Pseudomonas aeruginosa* infections resistant to carbapenem.

# BRII-672 (ORA vance<sup>TM</sup>)

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- o Qpex announced in early 2022 that BRII-672, in combination with a non-disclosed oral beta-lactam antibiotic, received QIDP designation by the U.S. FDA.
- o Preclinical data and interim Phase 1 clinical results were presented at IDWeek in October 2022.
- o In the fourth quarter of 2022, Qpex completed the first-in-human Phase 1 study in the U.S. No subjects discontinued treatment due to adverse events and no serious adverse events were observed in this Phase 1 SAD study.
- o In December 2022, we submitted a pre-IND to the NMPA in China seeking regulatory guidance around a development plan for BRII-672 in China.

# • BRII-636 (OMNIvance<sup>®</sup>)

- o In early 2022, Qpex announced that BRII-636 received QIDP designation by the U.S. FDA.
- o Qpex completed a first-in-human Phase 1 study and a drug-drug interaction study and presented findings at IDWeek in the fourth quarter of 2022. This Phase 1 MAD study indicated that overall, BRII-636 (xeruborbactam), alone and in combination with meropenem, was well tolerated.

# NTM Lung Disease Program (Licensed from AN2)

# • BRII-658 (epetraborole)

- o Our Partner AN2 is advancing a pivotal Phase 2/3 clinical trial for treatment-refractory MAC lung disease.
- o AN2 also completed and reported topline results from its Phase 1 bridging study designed to evaluate the pharmacokinetics, safety and tolerability of oral epetraborole in Japanese subjects.

# COVID-19 Program (Internally discovered)

- Amubarvimab/romlusevimab combination therapy (formerly BRII-196 and BRII-198 combination therapy)
  - o Following commercial launch in China since July 2022, the Company sold substantially all available products of the amubarvimab/romlusevimab combination, with distribution to 25 provinces and 358 hospitals, with a revenue of RMB51.6 million. And as part of its commitment to ensuring humanitarian access and contributing to the containment of the pandemic outbreak, the Company donated nearly 3,000 doses for emergency use to 21 cities and 22 hospitals in China prior to the commercial launch.
  - o In January 2023, our amubarvimab/romlusevimab combination is the recommended antiviral treatment for COVID-19 in both the 10th COVID-19 Diagnosis and Treatment Guideline and the 4th COVID-19 Diagnosis and Treatment Protocol for Severe/Critical Cases.
  - o The Company has made the decision to discontinue its amubarvimab/romlusevimab antibody combination program and has stopped manufacturing efforts in order to redirect resources to high-priority programs. This determination is based on constantly evolving COVID-19 trends including the upcoming expiration of the federal Public Health Emergency by the U.S. Department of Health and Human Services' in May 2023, as well as protracted regulatory inspections at our CDMO sites. The Company is working with the U.S. FDA to withdraw the EUA application at an appropriate time following the completion of activities required by the regulatory authority and also with the China's NMPA to withdraw the BLA in the third quarter of 2023 once all necessary regulatory requirements have been completed. No significant revenue is expected in the future from the commercialization of amubarvimab/romlusevimab combination either in China or in the U.S. or other territories.

# **Other Corporate Developments**

- We expanded our executive leadership team and strengthened our Board structure and corporate development initiatives, with the additions of Dr. Ankang Li, Chief Strategy Officer and Chief Financial Officer, to the Board as an executive Director and the chair of the Strategy Committee, and Dr. Taiyin Yang as an independent non-executive Director and the co-chair of the Audit and Risk Committee. New additions to the Brii Bio senior leadership team included Dr. Susannah Cantrell, Chief Business Officer, Dr. Eleanor de Groot, Chief Technology Officer, Dr. Aleksandar Skuban, Central Nervous System Diseases Therapy Area Head, and Karen D. Neuendorff, Chief People Officer.
- We strengthened the China leadership team, which included the appointments of Dr. Qing Zhu as our Head of China Research and Development, and Mr. Rico Liang as our General Manager, Greater China.
- The Company was added to the MSCI China Small Cap Index in Hong Kong in May 2022. The index is designed to measure the performance of the China market's small-cap segment and is widely recognized by the international financial community as a benchmark for global institutional investors seeking to optimize their investment portfolios.

- We continued to foster partnerships with key maternal health advocacy groups to address patients' needs and preferences in the U.S., including supporting the Postpartum Support International's Climb Out of the Darkness event, sponsoring the 20/20 Mom Annual Forum, the Maternal Mental Health Now, the 35th Annual Postpartum Support International Conference and the 2022 Black Maternal & Mental Health Summit.
- The Company continues to receive broad industry recognition for its corporate and clinical development accomplishments across more than ten awards and feature lists, including "50 Women in Tech" by Forbes China, "2022 Annual Biotechnology Innovation" by China Times, "Top 10 Chinese Pharmaceutical Listed Companies in ESG Investment Value in 2022" by Healthcare Executives, "2022-2023 Gold Bell Seal for Workplace Mental Health" by Mental Health America, etc. We also received an "A" rating by MSCI ESG Rating, which is a globally recognized assessment of a company's resilience to long-term ESG risks.

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, 2022

	NOTES	Year e Decemb 2022 <i>RMB'000</i>	
Revenue Other income Other gains and losses, net Research and development expenses Administrative expenses Selling and marketing expenses Fair value loss on financial liabilities at fair	4 5	51,626 107,857 (12,289) (440,634) (168,629) (26,861)	99,032 45,062 (494,615) (208,404) -
value through profit or loss (" <b>FVTPL</b> ") Finance costs Listing expenses		(851)	(3,598,847) (1,175) (32,137)
Loss before tax Income tax expense	6 7	(489,781)	(4,191,084)
Loss for the year		(489,781)	(4,191,084)
<b>Other comprehensive income (expense)</b> <i>Items that will not be reclassified to profit or loss:</i> Exchange differences on translation from			
functional currency to presentation currency Fair value loss on equity instrument at fair value		297,388	23,833
through other comprehensive income ("FVTOCI")		(30,110)	(6,072)
Item that may be reclassified subsequently to profit or loss: Exchange differences arising on translation of		267,278	17,761
foreign operations		(15,953)	(75,628)
Other comprehensive income (expense) for the year		251,325	(57,867)
Total comprehensive expense for the year		(238,456)	(4,248,951)
Loss for the year attributable to: Owners of the Company Non-controlling interests		(484,312) (5,469)	(4,163,849) (27,235)
		(489,781)	(4,191,084)
Total comprehensive expense for the year attributable to: Owners of the Company Non-controlling interests		(232,987) (5,469)	(4,221,716) (27,235)
		(238,456)	(4,248,951)
Loss per share – Basic and diluted (RMB)	8	(0.67)	(9.48)

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT DECEMBER 31, 2022

		As at December 31,		
	NOTES	2022 <i>RMB'000</i>	2021 RMB '000	
Non-current assets Property, plant and equipment Right-of-use assets Intangible assets Financial assets at FVTPL Equity instrument at FVTOCI Rental deposits	10	7,345 12,177 146,887 139,794 6,234 2,513 314,950	12,573 20,862 9,506 117,790 34,241 2,786 197,758	
<b>Current assets</b> Deposits, prepayments and other receivables Restricted bank deposits Time deposits with original maturity over three months Cash and cash equivalents	10	77,640 1,875 1,806,812 1,190,572	58,882 319 499,647 2,855,093	
		3,076,899	3,413,941	
<b>Current liabilities</b> Other payables Lease liabilities Deferred income	11	164,937 9,500 54,676 229,113	218,860 8,969 52,884 280,713	
Net current assets		2,847,786	3,133,228	
Total assets less current liabilities		3,162,736	3,330,986	
Non-current liabilities Lease liabilities Deferred income		3,156 2,083	12,647 7,083	
		5,239	19,730	
Net assets		3,157,497	3,311,256	
<b>Capital and reserves</b> Share capital Share premium and reserves		24 3,194,590	23 3,342,881	
Equity attributable to owners of the Company Non-controlling interests		3,194,614 (37,117)	3,342,904 (31,648)	
Total equity		3,157,497	3,311,256	

#### **NOTES TO THESE CONSOLIDATED FINANCIAL STATEMENTS** FOR THE YEAR ENDED DECEMBER 31, 2022

#### 1. GENERAL INFORMATION

Brii Biosciences Limited (the "**Company**") was incorporated in the Cayman Islands as an exempted company with limited liability on December 8, 2017. The Company's shares were listed on the Main Board of The Stock Exchange of Hong Kong Limited on July 13, 2021 (the "Listing"). 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 and the United States of America (the "USA") 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 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 AMENDMENTS TO INTERNATIONAL FINANCIAL REPORTING STANDARDS ("IFRSs")

#### Amendments to IFRSs that are mandatorily effective for the current year

In the current year, the Group has applied the following 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, 2022 for the preparation of these consolidated financial statements:

Amendments to IFRS 3	Reference to the Conceptual Framework
Amendment to IFRS 16	Covid-19-Related Rent Concessions beyond June 30, 2021
Amendments to IAS 16	Property, Plant and Equipment – Proceeds before Intended Use
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract
Amendments to IFRSs	Annual Improvements to IFRSs 2018-2020

The application of these 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.

#### New and amendments to IFRSs in issue but not yet effective

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

IFRS 17 (including the June 2020 and December 2021 Amendments to IFRS 17)	Insurance Contracts <sup>1</sup>
Amendments to IFRS 10	Sale or Contribution of Assets between an Investor and its
and IAS 28	Associate or Joint Venture <sup>2</sup>
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback <sup>3</sup>
Amendments to IAS 1	Classification of Liabilities as Current or Non-current <sup>3</sup>
Amendments to IAS 1	Non-current Liabilities with Covenants <sup>3</sup>
Amendments to IAS 1	Disclosure of Accounting Policies <sup>1</sup>
and IFRS Practice Statement 2	
Amendments to IAS 8	Definition of Accounting Estimates <sup>1</sup>
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction <sup>1</sup>

- <sup>1</sup> Effective for annual periods beginning on or after January 1, 2023.
- <sup>2</sup> Effective for annual periods beginning on or after a date to be determined.
- <sup>3</sup> Effective for annual periods beginning on or after January 1, 2024.

The directors of the Company anticipate that the application of all these new and 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 as a whole. Accordingly, the Group has only one reportable segment and only entity-wide disclosures are presented.

#### Geographical information

All of the Group's non-current assets (excluding financial instruments) are located in the PRC and all of the Group's revenue from external customers are located in the PRC.

#### 4. **REVENUE**

In the current year, the Group derives its revenue from the sale of pharmaceutical products amounted to RMB51,626,000 (2021: nil). 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.

The pharmaceutical products sold during the year ended December 31, 2022 were initially put into production for research and development purpose before applying for new drug application. In common practice, these products would not be used for commercial purpose. However, the manufacturing process of these products was then validated by government authorities for the purpose of regulatory compliance. Following these regulatory approvals, the Group launched commercial sales for these products in July 2022. The costs for these products sold amounted to RMB33,216,000, amongst which RMB24,529,000 and RMB8,687,000 were recorded as the Group's research and development expenses for the year ended December 31, 2021 and 2022, respectively.

#### 5. OTHER INCOME

	Year ended December 31,		
	2022	2021	
	RMB'000	RMB'000	
Bank interest income	37,204	6,490	
Government grants (note)	70,310	92,542	
Others	343		
	107,857	99,032	

*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, government grants of RMB67.1 million (2021: RMB70.6 million) were received. As at December 31, 2022, government grants of RMB56.8 million (2021: RMB60.0 million) have not fully met the relevant conditions and therefore are deferred and recorded as deferred income.

	Year ended December 31,		
	2022	2021	
	RMB'000	RMB'000	
Loss before tax for the year has been arrived at after charging:			
Depreciation of property, plant and equipment	5,228	4,962	
Depreciation of right-of-use assets	8,685	9,584	
Amortisation of intangible assets (included in			
research and development expenses)	3,119	2,716	
Auditors' remuneration	1,896	2,018	

#### 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.

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,		
	2022	2021	
Loss for the year attributable to owners of the Company for the			
purpose of basic and diluted loss per share (RMB'000)	(484,312)	(4,163,849)	
Weighted average number of ordinary shares for the purpose of			
basic and diluted loss per share ('000)	723,478	439,047	

For the year ended December 31, 2022, the weighted average number of ordinary shares for the purpose of basic and diluted loss per share has excluded the unvested restricted ordinary shares and unvested restricted share units (2021: unvested restricted ordinary shares) of the Company.

The computation of diluted loss per share for the year ended December 31, 2022 did not assume the exercise of share options, the vesting of unvested restricted share units and unvested restricted ordinary shares since their assumed exercise and vesting would result in a decrease in loss per share.

The computation of diluted loss per share for the year ended December 31, 2021 did not assume the exercise of share options, the vesting of unvested restricted ordinary shares, and did not assume the exercise of the overallotment option for the year ended 31 December 2021 since their assumed exercise and vesting would result in a decrease in loss per share.

#### 9. **DIVIDENDS**

No dividend was paid or declared by the Company during the year ended December 31, 2021 and 2022, nor has any dividend been proposed subsequent to the end of the reporting period.

#### 10. RENTAL DEPOSITS/DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

As at December 31,		
2022	2021	
RMB'000	RMB'000	
19,589	7,365	
2,842	2,786	
46,172	45,537	
8,785	4,873	
2,765	1,107	
80,153	61,668	
2 512	2 704	
,	2,786	
	58,882	
80,153	61,668	
	2022 <i>RMB'000</i> 19,589 2,842 46,172 8,785 2,765 80,153 2,513 77,640	

#### 11. OTHER PAYABLES

As at December 31,		
2022 <i>RMB'000</i>	2021 <i>RMB</i> '000	
113,531	44,111	
/	1,042	
1,059	1,178	
1,861	1,653	
31,721	23,840	
3,397	136,835	
11,143	10,201	
164,937	218,860	
	2022 <i>RMB'000</i> 113,531 2,225 1,059 1,861 31,721 3,397 11,143	

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:

	2022 <i>RMB'000</i>	2021 <i>RMB`000</i>
0-30 days	12,285	43,327
31-60 days	5,883	780
61-90 days	2,958	4
Over 90 days	92,405	
	113,531	44,111

#### 12. EVENT AFTER THE REPORTING PERIOD

Silicon Valley Bank ("**SVB**") was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. The Company and the Group held less than 9% of its total cash and bank balances (including cash and cash equivalents and time deposits with original maturity over three months) at SVB at February 28, 2023 (based on the Company's and the Group's unaudited management accounts). Up to the date of approving these consolidated financial statements, the Company and the Group have full access to all the bank balances at SVB.

# MANAGEMENT DISCUSSION AND ANALYSIS

#### **OVERVIEW**

Since our inception, we have been on a mission to tackle the biggest public health challenges of our time through breakthrough innovation driven by patient insight. As the Company advances to the next stage of development, we have expanded our global leadership team, adding diversified talent with extensive expertise.

We are well-positioned to leverage each of our senior executives' unique leadership skills and industry experience to extensively execute across our broad therapeutic area development strategy. To realize this vision, we are leveraging our business model, which combines internal discovery and in-licensing, while actively advancing our clinical programs. Our cross-border organic operations are one of our competitive advantages and position us for accelerated commercialization opportunities. With our presence in both geographies, we can utilize our respective strengths to accelerate the discovery, development and delivery of innovative medicines that have the potential to improve the health of patients around the world.

United in collaborative operations and a shared goal, our program emphasis in China strategically focused on our HBV functional curative therapy program as this is the area where we see opportunity to contribute significant and meaningful therapeutic impact for patients in the region. In addition, we launched for commercial availability our long-acting antibody combination therapy for COVID-19 in China since July 2022. In the U.S., we are centered on our internally discovered CNS programs for the treatment of PPD/MDD, leveraging our strong in-house R&D capabilities. We are also looking to partner our internally discovered HIV programs with other U.S. biotechnology development leaders.

Our lead program is designed to find a functional cure for chronic HBV infections, which have a disproportional health impact in China. This is one of our most advanced programs and we hold a rich pipeline of in-licensed assets from our partner Vir and VBI where we hold development and commercialization rights in Greater China. The newly introduced BRII-877, also called VIR-3434, a strong HBV-neutralizing monoclonal antibody showing great potential from the current studies led by Vir, further strengthen our core HBV portfolio. Leveraging our robust HBV assets, we are poised to be the leading player to find a functional cure for HBV, giving us a potential first-to-market advantage.

As an important target area of public health, it is known that depression brings heavy social burdens and is frequently observed not only in patients with CNS diseases but also with other chronic diseases. In 2022, we continued to build our internal discovery team to progress our U.S. programs with BRII-296 for the treatment of postpartum depression, anxiety and other depressive disorders, as well as BRII-297, a new chemical entity for anxiety and depressive disorders. Early feedback from physicians and patient communities has been very positive and reinforces the potential for BRII-296 to be a first-of-its-kind single-injection treatment option for PPD and MDD treatment in the U.S. In 2023, we plan to expand clinical indications for BRII-296 as well as initiate a first-in-human PK, safety, and tolerability study with BRII-297.

Given the widespread incidence of HIV around the word, we discovered and began developing a long-acting, once-weekly single tablet regimen for HIV patients with an initial focus in the U.S. We are currently exploring partnership opportunities for continued development of the long-acting treatment with our internally developed candidate BRII-732 as combination therapy. We also selected a new clinical candidate, BRII-753, as a long-acting subcutaneous injection therapy with the goal to extend the dosing schedule to once monthly, once quarterly or once semi-annually.

For the MDR/XDR program, our partners diligently advance their clinical development programs in the U.S., while we are working closely with them to track and inform the strategic development of our in-licensed therapeutic candidates for further development in China, which we plan to begin later this year.

In response to the unprecedented global COVID-19 pandemic and its subsequent variants, and consistent with our commitment to tackle public health challenges, we completed the development of our long-acting neutralizing antibody cocktail therapy for the treatment of COVID-19, which became commercially available in China since July 2022. Considering the constantly evolving COVID-19 trends and policy updates, as well as protracted regulatory inspections at our CDMO sites, we have made the decision to discontinue the amubarvimab/romlusevimab antibody combination program for COVID-19 and have stopped manufacturing efforts in order to redirect resources to high-priority programs.

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

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

# **Pipeline Summary**

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

Our strategic product pipeline is derived from (i) utilizing our in-house R&D capabilities to discover and develop our own innovative products and (ii) establishing collaborative licensing arrangements with carefully selected partners, whereby we in-license the Greater China rights to their important assets and lead the clinical development in China, playing an integral role in the global development of such assets.

The following table sets forth the status of our key product candidates as of the date of this announcement:

Indication	Program	Preclinical	IND	Phase 1	Phase 2	Phase 3	NDA/BLA	Our Rights	Partners
Infectious Disease Pr	Infectious Disease Programs								
	BRII-179 (VBI-2601)/BRII-835 (VIR-2218) Combination							Greater China*	
Hepatitis B	BRII-179 (VBI-2601)/PEG-IFN- $\alpha$ Combination							Greater China*	VBI
	BRII-877 (VIR-3434) <sup>(1)</sup>							Greater China*	NIR
HIV	BRII-732							Global	Internally discovered
niv	BRII-753							Global	Internally discovered
MDR/XDR	BRII-672 (ORAvance)(2)							Greater China*	O. QPEX
Gram-negative Bacterial	BRII-693 (QPX9003) <sup>(2)</sup>							Greater China*	O. gpex
Infections	BRII-636 (OMNIvance)(2)							Greater China*	O. OPEX
NTM Lung Disease	BRII-658 (Epetraborole) <sup>(3)</sup>							Greater China*	<b>AN2</b> Therapeutics
Central Nervous System Disease Programs									
PPD	BRII-296							Global	Internally discovered
Anxiety & Other Depressive Disorders	BRII-296							Global	Internally discovered
Anxiety & Depressive Disorders	BRII-297							Global	Internally discovered

\* Greater China – Mainland China, Macau, Hong Kong and Taiwan

Source: Company information

Notes:

- (1) The Phase 2 clinical trials have been conducted by Vir
- (2) To this date, the development and clinical trials have been conducted by Qpex
- (3) To this date, the development and clinical trials have been conducted by AN2

As of the date of this announcement, we had more than 10 product candidates, presenting a mix of in-licensed and self-discovered candidates. Our internally discovered drug candidates for which we hold global rights include:

- o BRII-296 for the treatment of PPD/MDD, anxiety and other depressive disorders;
- o BRII-297 for the treatment of various anxiety and depressive disorders;
- o BRII-732 and BRII-753 for the treatment of HIV; and
- o Amubarvimab/romlusevimab combination therapy for the treatment of COVID-19 (global rights are collectively held by us and our non-wholly owned subsidiary TSB Therapeutics).

Our in-licensed drug candidates for which we hold the Greater China rights include:

- o BRII-179 (VBI-2601), BRII-835 (VIR-2218) and BRII-877 (VIR-3434) for the development of a functional cure for HBV;
- o BRII-636, BRII-672 and BRII-693 for the treatment of MDR/XDR gram-negative infections; and
- o BRII-658 for the treatment of NTM lung disease, with an initial focus on treatment of treatment-refractory *mycobacterium avium complex* lung disease.

#### **BUSINESS REVIEW**

During the Reporting Period, we rapidly advanced our product pipeline and business operations. Specifically, we advanced our programs for HBV, PPD/MDD, HIV, MDR/XDR gram-negative infections and NTM lung disease. We also launched our first commercial product in China for the treatment of COVID-19, as well as broadened the depth of our senior executive leadership team. Our primary achievements as of the date of this announcement along with our planned next steps and upcoming milestones include:

#### **Our Product Candidates**

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

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

#### BRII-179 (VBI-2601) in Combination with BRII-835 (VIR-2218) (Study conducted by Brii Bio)

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

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

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

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

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

#### Next Achievements and Upcoming Readouts

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

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

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

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

• In December 2022, we completed patient enrollment of approximately 120 patients in part one of a Phase 2 combination trial evaluating the addition of BRII-179 (VBI-2601) in chronic HBV patients already receiving PEG-IFN-α and NRTI treatment.

#### Next Achievements and Upcoming Readouts

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

# VIR-2218 (BRII-835) in Combination with PEG-IFN-α (Study conducted by Vir)

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

- Vir presented data at the International Liver Congress in June 2022, showing longer treatment duration of monthly VIR-2218 (BRII-835) results in deeper and more sustained reductions in HBsAg in participants with chronic HBV infection.
- In November 2022, Vir announced end-of-treatment data from an ongoing Phase 2 trial of combination of VIR-2218 (BRII-835) with PEG-IFN-α (lasting for 48 weeks) at the AASLD 2022 meeting, which demonstrated that approximately 31% of patients with chronic HBV infection achieved HBsAg seroclearance with hepatitis B antibodies seroconversion with no new safety signals.

#### Next Achievements and Upcoming Readouts

• Additional data from the Phase 2 study led by Vir are expected in the first half of 2023.

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

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

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

• In July 2022, we announced that the Company exercised its option to in-license BRII-877 (VIR-3434) for exclusive development and commercialization rights in Greater China as part of our broader collaboration with Vir.

• In November 2022, Vir presented initial end-of-treatment data at AASLD's The Liver Meeting<sup>®</sup> from Part A of the ongoing Phase 2 MARCH study evaluating VIR-2218 (BRII-835) in combination with VIR-3434 (BRII-877) in participants with chronic HBV infection who received NRTI therapy. The data indicated additive HBsAg reductions from VIR-2218 (BRII-835) and VIR-3434 (BRII-877) with combination regimens achieving a much greater HBsAg reduction than either alone in all patients with no safety signals.

# Next Achievements and Upcoming Readouts

- Additional data from Part A of Vir's ongoing Phase 2 MARCH trial are expected in the first half of 2023.
- Initial data to evaluate VIR-2218 (BRII-835) and VIR-3434 (BRII-877) with or without PEG-IFN- $\alpha$  are expected in the second half of 2023 from Part B of Vir's ongoing Phase 2 MARCH trial.
- We are working closely with CDE of the NMPA to initiate a Phase 1 study of BRII-877 (VIR-3434) in China.

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

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

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

# <u>Clinical Development Milestones and Achievements as at the Date of This Announcement</u>

- In September 2022, we announced positive topline results from our Phase 1 study for BRII-296 with data that demonstrated a single administration of the investigational therapy at 600 mg delivered a favorable PK profile and was safe and well-tolerated in healthy subjects.
- Early feedback from physicians and patient communities has been very positive and reinforces the potential for a first-of-its-kind single-injection treatment option for PPD in the U.S.

# Next Achievements and Upcoming Readouts

- We are working closely with the U.S. FDA to align and agree on the PPD treatment protocol in preparation for a Phase 2 POC study.
- We are actively working to expand the clinical indications for BRII-296 and plan to initiate additional Phase 2 studies in the U.S. by the end of 2023.

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

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

• We have conducted IND-enabling studies with BRII-297 targeting various anxiety and depressive disorders. In preparation for a first-in-human study, during the first half of 2022, we completed the formulation of the development and short-term toxicity studies.

# Next Achievements and Upcoming Readouts

• We plan to initiate a first-in-human PK, safety and tolerability study with BRII-297 in Australia in the first half of 2023.

# HIV Program (Internally discovered)

The Company is seeking partners to collaborate on the development of a once-weekly oral single-tablet regimen, BRII-732, for the treatment or prevention of HIV. We are also seeking to develop partnership for a novel low volume, subcutaneous injection therapy, BRII-753, with potential to dose monthly to every six months. Both compounds demonstrate considerable promise to serve as a key component for long-acting HIV treatment regimens that will offer more discreet and convenient options for patients living with HIV, and as monotherapy for HIV prevention.

**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.

# <u>Clinical Development Milestones and Achievements as at the Date of This Announcement</u>

- We completed our Phase 1 SAD/MAD study of BRII-732 in May 2022.
- In October 2022, we presented positive Phase 1 data showing that BRII-732 demonstrated an acceptable safety and tolerability profile, as well as a favorable and linear PK profile that achieved therapeutic targets in healthy volunteers, reinforcing its potential as an oral once-weekly therapy for the treatment of HIV infections.
- In December 2022, we were notified by the U.S. FDA that it had lifted the clinical hold on the Company's planned Phase 1 study to investigate a lower oral dose of once-weekly BRII-732.

# Next Achievements and Upcoming Readouts

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

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

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

• The Company selected a new clinical candidate, BRII-753, as a long-acting subcutaneous injection therapy with the goal to extend the dosing schedule to once monthly, once quarterly or twice-yearly.

**BRII-778:** is an extended-release formulation of an U.S. FDA-approved NNRTI, Edurant (rilpivirine hydrochloride). Edurant, an instant-release formulation of rilpivirine, has exhibited antiviral activity against a broad panel of HIV's most common strains. BRII-778, like all NNRTIs, binds to the NNRTI binding site which is a flexible allosteric pocket located at a site adjacent to the DNA polymerizing processing site, resulting in conformational changes and altered function of reverse transcriptase.

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

- We completed the final clinical study report for our BRII-778 Phase 1 SAD/MAD trial in June 2022.
- Based on the PK data from a completed Phase 1 study, which determined that additional development work was required to achieve optimal PK targets for the treatment of HIV, thus the Company has made the decision to discontinue the development of BRII-778.

# MDR/XDR Gram-negative Bacteria Infections Program (Licensed from Qpex)

We are developing MDR/XDR therapies in collaboration with our partner Qpex as part of its global development plan. Based on a licensing agreement with Qpex, we have the exclusive rights to develop and commercialize BRII-636, BRII-672 and BRII-693 in Greater China.

Qpex is progressing BRII-636, BRII-672 and BRII-693 in parallel with a goal of moving each to global Phase 3 studies, at which time we will participate in the China-based arm of the global research protocols. BRII-636, BRII-672 and BRII-693 candidates all obtained QIDP designation from the U.S. FDA, which may receive incentives in the future.

**BRII-693** (**QPX-9003**): 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 hospital-administered intravenous antibiotics.

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

- Qpex announced in early 2022 that BRII-693 received QIDP designation by the U.S. FDA.
- In October 2022, Qpex presented interim Phase 1 result at IDWeek from its completed first-in-human clinical study, demonstrating that BRII-693 was safe and well tolerated at all doses tested, and the result supports continued development of BRII-693 for the treatment of Acinetobacter baumannii and Pseudomonas aeruginosa infections resistant to carbapenem.

# Next Achievements and Upcoming Readouts

- Qpex continues to work closely with the U.S. FDA to align its next steps in clinical development.
- We plan to submit a pre-IND to the NMPA in the first half of 2023 for the development of BRII-693 in China.

**BRII-672** (**ORAvance**<sup>TM</sup>) is a prodrug of BRII-636 and an oral BLI under development for the treatment of MDR/XDR Gram-negative bacterial infections. These agents were discovered by our partner Qpex as part of its expertise in BLIs, using the boron atom as a part of its pharmacophore.

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

- Qpex announced in early 2022 that BRII-672, in combination with a non-disclosed oral beta-lactam antibiotic, received QIDP designation by the U.S. FDA.
- Preclinical data and interim first-in-human Phase 1 clinical results were presented at IDWeek in October 2022.
- In the fourth quarter of 2022, Qpex completed the first-in-human Phase 1 study in the U.S. No subjects discontinued treatment due to adverse events and no serious adverse events were observed in this Phase 1 SAD study.
- In December 2022, we submitted a pre-IND to the NMPA in China seeking regulatory guidance around a development plan for BRII-672 in China.

#### Next Achievements and Upcoming Readouts

• Qpex continues to work closely with the U.S. FDA to align its next stages in clinical development.

**BRII-636** (**OMNIvance**<sup>®</sup>): intravenously administered novel cyclic boronic acid derived broad-spectrum inhibitor under development for the treatment of MDR/XDR Gram-negative bacterial infections.

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

- In early 2022, Qpex announced that BRII-636 received QIDP designation by the U.S. FDA.
- Qpex completed a first-in-human Phase 1 study and a drug-drug interaction study and presented findings at the IDWeek conference in the fourth quarter of 2022. This Phase 1 MAD study indicated that overall, BRII-636 (xeruborbactam), alone and in combination with meropenem, at doses associated with efficacy in animal models of infection was well-tolerated.

#### Next Achievements and Upcoming Readouts

• Qpex continues to work closely with the U.S. FDA to align its next stages in clinical development.

# NTM Lung Disease Program (Licensed from AN2)

Brii Bio's strategic partner, AN2, is developing epetraborole (BRII-658) as a once-daily oral treatment for patients with chronic NTM lung disease, with an initial focus on treatment-refractory *Mycobacterium avium complex* lung disease, which is the subpopulation of MAC lung disease with the highest unmet medical needs for new therapies. We hold a license to develop, manufacture and commercialize epetraborole (BRII-658) in Greater China.

**BRII-658** (epetraborole) is in development as a once-daily oral treatment for patients with chronic NTM lung disease, with an initial focus on treatment of refractory MAC lung disease. It is a boron-containing, small molecule inhibitor of mycobacterial leucyl-tRNA synthetase, or LeuRS, an enzyme that inhibits protein synthesis.

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

# **BRII-658** (epetraborole)

- Our partner, AN2, is advancing a pivotal Phase 2/3 clinical trial for treatment-refractory MAC lung disease.
- AN2 also completed and reported topline results from its Phase 1 bridging study designed to evaluate the pharmacokinetics, safety and tolerability of oral epetraborole in Japanese subjects.

# COVID-19 Program (Internal discovered in collaboration with Tsinghua University and Third People's Hospital of Shenzhen through our subsidiary, TSB Therapeutics)

Amubarvimab and romlusevimab are non-competing SARS-CoV-2 monoclonal neutralizing antibodies derived from convalesced COVID-19 patients. They have been specifically engineered to reduce the risk of antibody-dependent enhancement and prolong the plasma half-life for potentially more durable treatment effect.

Approved by the China's NMPA in December 2021, our long-acting amubarvimab/romlusevimab cocktail therapy is approved to be administered by intravenous infusion in two sequential doses for the treatment in adults and pediatric patients (age 12-17 weighing at least 40 kg) of mild- and normal-type COVID-19 at high risk for progression to severe disease, including hospitalization or death. The indication of pediatric patients (age 12-17 weighing at least 40 kg) is under conditional approval. In January 2023, the National Health Commission of China reiterated the amubarvimab/romlusevimab combination in its COVID-19 Diagnosis and Treatment Guidelines (10th Edition) for the treatment of COVID-19 and the 4th COVID-19 Diagnosis and Treatment Protocol for Severe/Critical Cases. The live virus testing data as well as pseudovirus testing data from multiple independent laboratories have demonstrated that the amubarvimab/romlusevimab combination retains activity against commonly identified SARS-CoV-2 variants such as B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.429 (Epsilon), B.1.617.2 (Delta), AY.4.2 (Delta Plus), C.37 (Lambda), B.1.621 (Mu), B.1.1.529-BA.1 (Omicron) and BA.1.1, BA.2, BA.2.12.1, BA.4/5, BF.7 (Omicron subvariants).

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

- Following commercial launch in China since July 2022, we sold substantially all available products of the amubarvimab/romlusevimab combination, with a revenue of RMB51.6 million and availability in over 25 provinces and more than 358 hospitals nationwide. And as part of its commitment to ensuring humanitarian access and contributing to the containment of the pandemic outbreak, the Company donated nearly 3,000 doses for emergency use to 21 cities and 22 hospitals in China prior to the commercial launch.
- In January 2023, the amubarvimab/romlusevimab combination is the recommended antiviral treatment for COVID-19 in both the 10th COVID-19 Diagnosis and Treatment Guideline and the 4th COVID-19 Diagnosis and Treatment Protocol for Severe/Critical Cases.

• The Company has made the decision to discontinue its amubarvimab/romlusevimab antibody combination program and has stopped manufacturing efforts in order to redirect resources to high-priority programs. This determination is based on constantly evolving COVID-19 trends including the upcoming expiration of the federal Public Health Emergency by the U.S. Department of Health and Human Services in May 2023, as well as protracted regulatory inspections at our CDMO sites. The Company is working with the U.S. FDA to withdraw the EUA application at an appropriate time following the completion of activities required by the regulatory authority and also with the China's NMPA to withdraw the BLA in the third quarter of 2023 once all necessary regulatory requirements have been completed. No significant revenue is expected in the future from the commercialization of amubarvimab/ romlusevimab combination either in China or in the U.S. or other territories.

#### **Other Corporate Developments**

- We expanded our executive leadership with appointments that strengthened our Board structure and corporate development initiatives, with the additions of Dr. Ankang Li, Chief Strategy Officer and Chief Financial Officer, to the Board as an executive Director and the chair of the Strategy Committee, and Dr. Taiyin Yang as an independent non-executive Director and the co-chair of the Audit and Risk Committee. New additions to the Brii Bio senior leadership team included Dr. Susannah Cantrell, Chief Business Officer, Dr. Eleanor de Groot, Chief Technology Officer, Dr. Aleksandar Skuban, Central Nervous System Diseases Therapy Area Head, and Karen D. Neuendorff, Chief People Officer.
- We strengthened the China leadership team, which included the appointments of Dr. Qing Zhu as Head of China R&D, and Mr. Rico Liang as General Manager, Greater China.
- In May 2022, the Company was added to the MSCI China Small Cap Index, an international benchmark for global institutional investors seeking to optimize their investment portfolios.
- We commercially launched amubarvimab/romlusevimab combination as a long-acting COVID-19 neutralizing antibody in China and formed strategic partnership with China Resources Pharmaceutical Commercial Group to advance the commercialization of amubarvimab/romlusevimab combination therapy.
- We foster partnerships with key maternal health advocacy groups to address patients' needs and preferences in the U.S., including supporting the Postpartum Support International's Climb Out of the Darkness event, and sponsoring the 20/20 Mom Annual Forum, Maternal Mental Health Now, the 35th Annual Postpartum Support International Conference and the 2022 Black Maternal & Mental Health Summit.
- The Company continues to receive broad industry recognition for its corporate and clinical development accomplishments across more than ten awards and feature lists, including: "50 Women in Tech" by Forbes China, "2022 Annual Biotechnology Innovation" by China Times, "Top 10 Chinese Pharmaceutical Listed Companies in ESG Investment Value in 2022" by Healthcare Executives, "2022-2023 Gold Bell Seal for Workplace Mental Health" by Mental Health America, etc.
- In 2022, the Company also received an "A" rating from MSCI ESG Rating, a globally recognized assessment of a company's resilience to long-term ESG risks. We are committed to addressing the toughest public health challenges through ground-breaking innovation and insights, as well as enhancing the accessibility of innovative medicines. We have officially stepped into the patient advocacy space and incorporated patient advocacy in all aspects of our work of helping global patients. Our patient centricity plan to properly involve advocates in our drug development and discovery process has made great progress and we continue to make advancements in 2022. We are more dedicated than ever to environmental protection and adhere to the concept of green business.

# R&D

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

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

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

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

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

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

By design, our multi-pronged R&D strategies entail R&D expenses that vary with the number and scale of projects each year. Our R&D expenses were RMB440.6 million for the year ended December 31, 2022. 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

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

Our COVID-19 antibody cocktail therapy, amubarvimab/romlusevimab, was commercialized in China in July 2022. Substantially all available products have been sold, with a recognized revenue of RMB51.6 million and availability in 25 provinces and 358 hospitals nationwide.

As at the date of this announcement, beyond commercialization of our COVID-19 therapy, our efforts have focused on building our drug candidate pipeline. Most of our programs are in different stages of clinical development. As most of our candidates are engaged in ongoing clinical trials and the COVID-19 program is discontinued, we do not anticipate sales or commercialization of drug candidates in the immediate future.

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

#### **FUTURE DEVELOPMENT**

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

In 2022, we re-dedicated our focus to our core development programs in HBV in China, where we are an industry frontrunner, as well as our psychiatric disorders programs, where we are accelerating our clinical development in depressive disorders treatment in the U.S.

#### Our strategic priorities for 2023 are to:

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

#### **Subsequent Event**

# Business update related to Silicon Valley Bank ("SVB")

The Board is aware that Silicon Valley Bank was closed on March 10, 2023 by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("**FDIC**") as receiver. As disclosed in the announcement of the Company dated March 12, 2022, the Company and its subsidiaries held less than 9% of its total cash and bank balances (including cash, cash equivalents and time deposits with original maturity of up to 12 months with multi-tenor rates and flexibility for early uplift) at SVB as of February 28, 2023. On March 12, 2023, the Treasury of the United States, Federal Reserve of the United States, and FDIC jointly announced that all depositors with SVB will have access to all of their money at SVB starting Monday, March 13. Following such announcement and as the date of this announcement, the Company and its subsidiaries have full access to all the bank balances at SVB.

# FINANCIAL REVIEW

#### 1. **Revenue**

Our revenue derives from the successful commercial launch of our long-acting amubarvimab/ romlusevimab combination amounted to RMB51.6 million for the year ended December 31, 2022. Revenue is recognised when control of the goods has been transferred, being when the goods have been delivered to the specified location designated by the customers.

#### 2. Other income

	Year ended December 31,		
	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000	
Bank interest income	37,204	6,490	
Government grants Others	70,310 343	92,542	
	107,857	99,032	

Our other income increased by RMB8.9 million from RMB99.0 million for the year ended December 31, 2021 to RMB107.9 million for the year ended December 31, 2022. This was primarily attributable to the increase in the bank interest income increased by RMB30.7 million. The increase of bank interest income was partially offset by the decrease of government grants income of RMB22.2 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 decreased by RMB57.4 million from gains of RMB45.1 million for the year ended December 31, 2021 to losses of RMB12.3 million for the year ended December 31, 2022. The decrease was primarily attributable to the differences resulting from the depreciation in foreign currency exchange rates on the carrying amount of financial assets denominated in a foreign currency.

#### 4. Fair value loss on financial liabilities at FVTPL

Our fair value loss on financial liabilities at FVTPL decreased by RMB3,598.8 million from RMB3,598.8 million for the year ended December 31, 2021 to nil for the year ended December 31, 2022. Fair value loss on financial liabilities measured at FVTPL consists of the issues of our Series A, Series B, and Series C preferred shares issued or outstanding during the year ended December 31, 2021. The amount of loss represents the increase in fair value of the preferred shares.

After the automatic conversion of all preferred shares into Shares upon the closing of the Global Offering in July 2021, we did not recognize any further gains or losses on fair value changes from these preferred shares.

#### 5. Fair value loss on equity instrument at FVTOCI

Our fair value loss on equity instrument at FVTOCI increased by RMB24.0 million from loss of RMB6.1 million for the year ended December 31, 2021 to loss of RMB30.1 million for the year ended December 31, 2022. The amounts represent the decrease of fair value of equity instrument at FVTOCI which is a listed equity investment in a biopharmaceutical company listed in the USA. The decrease was primarily attributable to the drop of quoted market price.

#### 6. **R&D** expenses

	Year ended De	cember 31,
	2022 <i>RMB</i> '000	2021 <i>RMB</i> '000
Third-party contracting costs Employee costs Licensing fee Depreciation and amortization Others	253,020 169,544 6,728 2,745 8,597	367,069 117,134 6,453 2,716 1,243
Total	440,634	494,615

Our R&D expenses decreased by RMB54.0 million from RMB494.6 million for the year ended December 31, 2021 to RMB440.6 million for the year ended December 31, 2022. The decrease was primarily due to the decrease in third party contracting costs relating to COVID-19 programs, which was partially offset by an increase of RMB52.4 million in the employee costs for our continuous development in clinical.

#### 7. Administrative expenses

	Year ended De	ecember 31,
	2022 <i>RMB</i> '000	2021 <i>RMB</i> '000
Employee costs Professional fees	100,849 33,490	146,688 21,579
Depreciation and amortization Office expenses	14,315 2,992	14,546 3,750
Others	16,983	21,841
Total	168,629	208,404

Our administrative expenses decreased by RMB39.8 million from RMB208.4 million for the year ended December 31, 2021 to RMB168.6 million for the year ended December 31, 2022. This was primarily attributable to a decrease of RMB45.9 million in employee costs from RMB146.7 million for the year ended December 31, 2021 to RMB100.8 million for the year ended December 31, 2022. Such decrease was primarily attributable to the decrease in share-based compensation expenses.

In addition, our professional fees increased by RMB11.9 million mainly due to the professional services required as a listed company following the Global Offering.

#### 8. Selling and marketing expenses

Our selling and marketing expenses were RMB26.9 million for the year ended December 31, 2022.

This was primarily attributable to the commercialization of COVID-19 therapy.

#### 9. Liquidity and Capital resources

As at December 31, 2022, our bank and cash balances, including restricted bank deposits and time deposits, decreased to RMB2,999.3 million from RMB3,355.1 million as at December 31, 2021. The decrease is primarily due to payout of daily operations and third party contracting costs.

#### **10.** 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 the loss on fair value changes of the conversion feature of preferred shares (financial liabilities measured at fair value through profit or loss), share-based compensation expenses and listing 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 figure 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,		
	2022 <i>RMB</i> '000	2021 <i>RMB</i> '000	
Loss for the year Added:	(489,781)	(4,191,084)	
Fair value loss on financial liabilities at fair value			
through profit or loss	-	3,598,847	
Share-based compensation expenses	77,928	79,370	
Listing expenses		32,137	
Adjusted loss for the year	(411,853)	(480,730)	

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

	Year ended December 31,		
	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000	
R&D expenses for the year Added:	(440,634)	(494,615)	
Share-based compensation expenses	44,245	16,962	
Adjusted R&D expenses for the year	(396,389)	(477,653)	

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

	Year ended December 31,		
	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000	
Administrative expenses for the year Added:	(168,629)	(208,404)	
Share-based compensation expenses	25,448	62,408	
Adjusted administrative expenses for the year	(143,181)	(145,996)	

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

	Year ended December 31,		
	2022 <i>RMB'000</i>	2021 <i>RMB</i> '000	
Selling and marketing expenses for the year Added:	(26,861)	_	
Share-based compensation expenses	8,235		
Adjusted selling and marketing expenses for the year	(18,626)	_	

#### 11. Key financial ratios

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

	As at December 31, 2022	
Current ratio <sup>(1)</sup>	1,343%	1,215%
Gearing ratio <sup>(2)</sup>	NM	NM

(1) Current ratio is calculated using current assets divided by current liabilities as of the same date.

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

#### 12. Indebtedness

#### **Borrowings**

As at December 31, 2022, 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, 2022, 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, 2022, the Group had lease liabilities of RMB12.7 million recognized under IFRS 16.

#### 13. Significant investments, material acquisitions and disposals

As at December 31, 2022, we did not hold any significant investments. For the year ended December 31, 2022, we did not have material acquisitions or disposals of subsidiaries, associates, and joint ventures.

#### 14. Charge on the Group's assets

As at December 31, 2022, none of the Group's assets were charged with any parties or financial institutions (December 31, 2021: nil).

#### **15.** 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, 2022, the Group's restricted bank deposits, time deposits with original maturity over three months and bank balances and cash were denominated as to 40% in US dollars, 36% in Hong Kong dollars, and 24% in RMB.

#### **16.** Employees and remuneration

As at December 31, 2022, we had a total of 146 employees. The following table sets forth the total number of employees by function as at December 31, 2022:

	Number of employees	% of total
Function		
R&D	89	61.0%
Administration	43	29.5%
Selling and marketing	14	9.5%
Total	146	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.

The total remuneration cost incurred by the Group for the year ended December 31, 2022 was RMB294 million, as compared to RMB264 million for the year ended December 31, 2021.

# **17.** Treasury policy

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

#### **OTHER INFORMATION**

#### USE OF PROCEEDS FROM THE GLOBAL OFFERING

#### Use of Proceeds during the Reporting Period

On July 13, 2021, the Company was successfully listed on the Stock Exchange. The net proceeds received by the Group from the Global Offering and the partial exercise of the over-allotment option (after deducting underwriting fee and relevant expenses) amounted to approximately HK\$2.614 billion. During the Reporting Period, the Company had utilized such net proceeds in accordance with the purposes as set out in the Prospectus.

As of December 31, 2022, our Company has not yet fully utilized the net proceeds from the Global Offering (the "**Net Proceeds**") of approximately HK\$1,789.7 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. The 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 Prospectus	Original allocation of Net Proceeds as disclosed in the Prospectus HK\$ million	Original percentage of total Net Proceeds as disclosed in the Prospectus	Amount of utilized Net Proceeds as at December 31, 2022 <i>HK\$ million</i>	Amount of Unutilized Net Proceeds as at December 31, 2022 HK\$ 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 of December 31, 2022 HK\$ million
1. Used for our HBV functional cure programs	1,437.6	55%	307.3	1,130.3	1. Same as original	994.1	38.0%	686.8
<ul> <li>1.1 To fund ongoing and planned clinical trials and preparation for regulatory filings for BRII-179/BRII- 835 combination therapy in chronic HBV patients</li> </ul>	522.8	20%	62.1	460.7	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 (aggregate allocation of Net Proceeds to the original items 1.1 to 1.4 was HK\$1,280.8 million in total)	32% (aggregate percentage of total Net Proceeds of the original items 1.1 to 1.4 was 49% in total)	530.0
1.2 To fund planned clinical trials and preparation for regulatory filings for BRII179/PEG-IFN-α combination therapy in chronic HPV potients	418.2	16%	20.1	398.1	- (Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)

chronic HBV patients

Original use of proceeds as disclosed in the Prospectus	Original allocation of Net Proceeds as disclosed in the Prospectus HK\$ million	Original percentage of total Net Proceeds as disclosed in the Prospectus	Amount of utilized Net Proceeds as at December 31, 2022 HK\$ million	Amount of Unutilized Net Proceeds as at December 31, 2022 <i>HK\$ million</i>	Changed use of proceeds	Revised allocation of Net Proceeds HK\$ million	Revised percentage of total Net Proceeds	Revised amount of Unutilized Net Proceeds as of December 31, 2022 HK\$ million
1.3 To fund planned clinical trials and preparation for regulatory filings for BRII- 179 in combination with other drug candidates with complimentary mechanism of actions	209.1	8%	196.4	12.7	- (Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)
1.4 Used to fund additional ongoing and planned clinical trials and the preparation for registration filings for BRII-835	130.7	5%	28.7	102.0	- (Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)	(Consolidated into revised item 1.1)
1.5 Used for regulatory milestone payments for BRII-179	26.1	1%	-	26.1	1.2 Same as original 1.5	26.1	1%	26.1
1.6 Used for the launch and commercialization of BRII-179 (as a monotherapy and/or combination therapy)	130.7	5%	-	130.7	1.3 Used for the launch and commercialization of HBV curative treatment regimens	130.7	5%	130.7
<ol> <li>Used for our HIV programs, funding the ongoing and planned clinical trials and preparation for registration filings for BRII-778 and BRII- 732</li> </ol>	392.1	15%	105.3	286.8	2. 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	176.0	7%	70.7
3. Used for our MDR/XDR gram- negative infections programs	392.1	15%	34.1	358.0	3. Same as original	294.0	11%	259.9
<ul> <li>3.1 To fund the ongoing and planned clinical trials and preparation for registration filings for BRII-636, BRII- 672 and BBII-632</li> </ul>	235.2	9%	25.6	209.6	3.1 Same as original	234.5	9%	208.9

672 and BRII-693

3.2 Used for regulatory milestone payments for BRII-672 and BRII-693       156.9       6%       8.5       148.4       3.2 Same as original       59.5       2%       51.0         4. To fund the ongoing and planned finical trials and preparation for registration filings for BRII-296       130.6       5%       116.0       14.6       4. Used for our early-stage control for editors and planned non-continual trials and preparation for registration filings for BRII-296       19%       380.3         5. Used for our early-stage pipeline, business development initiatives, working capital and general corporate purposes       261.4       10%       264.1       -       5. Used for over early-stage acred to the pre-control for registration filings for BRII-296       392.0       15%       334.8         Total       2.613.80       10%       824.1       1.789.7       2.613.80       10%       57.2	Original use of proceeds as disclosed in the Prospectus	Original allocation of Net Proceeds as disclosed in the Prospectus HK\$ million	Original percentage of total Net Proceeds as disclosed in the Prospectus	Amount of utilized Net Proceeds as at December 31, 2022 <i>HK\$ million</i>	Amount of Unutilized Net Proceeds as at December 31, 2022 <i>HK\$ million</i>	Changed use of proceeds	Revised allocation of Net Proceeds HK\$ million	Revised percentage of total Net Proceeds	Revised amount of Unutilized Net Proceeds as of December 31, 2022 HK\$ million
planed clinical trials and preparation for registration filings for BRII-296 CNS programs, funding the ongoing and planed non- clinical studies, clinical studies, clinical studies, clinical studies, clinical trials and preparation for registration filings for BRII-296, BRII- 297 and other pre- clinical candidates 5. Used for our early-stage pipeline, business development initiatives, working capital and general corporate purposes general corporate purposes corporate purposes	milestone payments for BRII-636, BRII-672 and	156.9	6%	8.5	148.4	3.2 Same as original	59.5	2%	51.0
5. Used for our early-stage 261.4 10% 264.1 – 5. Used for 392.0 15% 334.8 pipeline, business development initiatives, working capital and general corporate purposes development activities for pipeline expansion 6. Used for working 261.4 10% 57.2 capital and general corporate purposes	<ol> <li>To fund the ongoing and planned clinical trials and preparation for registration</li> </ol>	130.6	5%	116.0	14.6	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	496.3	19%	380.3
	pipeline, business development initiatives, working capital and	261.4	10%	264.1	-	5. Used for discovery and business development activities for pipeline expansion 6. Used for working			
	Total	2,613.80	100%	824.1	1,789.7	corporate purposes	2,613.80	100%	1,789.7

The Company expects to fully utilize the Unutilized Net Proceeds after the proposed change by the end of 2025.

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

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

- a) The Company is building a novel and first-in-class clinical portfolio of HBV therapeutic candidates alongside our strategic partners that may be used in various combinations to improve the probability of achieving a high rate of functional cure for different subpopulations of HBV patients in China. Since the listing of Shares on the Stock Exchange in July 2021, the Company has exercised the option on BRII-877 to enhance its leading position in HBV functional cure development. In addition to BRII-179, BRII-835 and BRII-877 have progressed into multiple Phase 2 clinical studies and emerged as promising clinical candidates for HBV functional cure. The Company is taking a holistic approach to design development plans and future commercialization strategies for the existing HBV pipeline assets. Therefore, original items 1, 1.1, 1.2, 1.3, 1.4 and 1.6 have been consolidated and/or updated, and the allocation of the Unutilized Net Proceeds to fund such assets (i.e. original items 1.1, 1,2, 1,3, 1.4 and 1.6 above) is thus consolidated to reflect the approach.
- b) The Company and its strategic partner, Vir, are conducting various clinical trials to evaluate different combination regimens for HBV functional cure. This coordinated approach makes it possible for the Company to determine and prioritize the combination regimens with the highest probability of success earlier. Therefore, the allocation of the Unutilized Net Proceeds to fund the development of combination regimens is adjusted downwards to reflect the expected improved development efficiency.
- c) The Group has adjusted its focus of R&D resource allocation to concentrate its resources on the core pipeline products that possess greater strategic priority, and to reduce the resources devoted to non-core pipeline products after careful evaluation. Therefore, the portion of the Unutilized Net Proceeds allocated to original item 2 and 3 (non-core products) is adjusted downwards.
- d) The Company made the decision in the second half of 2022 to discontinue development of BRII-778 based on PK data from a completed Phase 1 study. The Company is exploring partnership opportunities to continue developing BRII-732 as part of a potential oral, once-weekly, long-acting combination treatment option for HIV patients. The Company continues to be committed to developing innovative long-acting treatment regimens for HIV patients and has selected BRII-753, a new clinical candidate discovered internally, as a long-acting subcutaneous injection therapy with the goal to extend the dosing schedule to once monthly, once quarterly or twice-yearly. The adjustment to the portion of the Unutilized Net Proceeds allocated to original item 2 have also considered the discontinuation of BRII-778 and the addition of BRII-753.
- e) The Company has made substantial progress in CNS programs since the listing of Shares on the Stock Exchange. The internally discovered CNS programs have become the Company's business focus in the U.S. The Company is in preparation for its Phase 2 POC study and is actively working to expand the clinical indications for BRII-296. It has also conducted IND-enabling studies with BRII-297 targeting various anxiety and depressive disorders and plans to initiate Phase 1 study in 2023. Therefore, original item 4 has been updated and a greater portion of the Unutilized Net Proceeds is re-allocated thereto to reflect the current strategic focus on the CNS programs and the expected increase in R&D activities in CNS, mainly due to the update in development plan for BRII-296 and the addition of BRII-297.

f) The Company has set out the strategic priority to expand its pipeline through in-house discovery and additional licensing options. In addition, considering our rapid development after the listing of Shares on the Stock Exchange, the Board considered that it would be appropriate to further divide original item 5 into revised items 5 and 6 to reflect the initiative in a standalone item, and reallocate additional Unutilized Net Proceeds to revised items 5 and 6.

The Board has considered that the strategic direction of the Company is still in line with the disclosures in the Prospectus in spite of the change in use of the Unutilized Net Proceeds as stated above. 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 change in the use of the Net Proceeds is fair and reasonable as this would allow the Company to deploy its financial resources more effectively and efficiently to advance the pipeline products of the Company, and is therefore in the best interest of our 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 our current and future development of market conditions and actual business needs.

# FINAL DIVIDEND

The Board did not recommend the payment of a final dividend for the year ended December 31, 2022.

# **CLOSURE OF THE REGISTER OF MEMBERS**

The Company will hold the AGM on Tuesday, June 20, 2023. The register of members of the Company will be closed from Thursday, June 15, 2023 to Tuesday, June 20, 2023, 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 14, 2023.

# **CORPORATE GOVERNANCE PRACTICES**

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

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

Under code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Accordingly, the appointment of Dr. Zhi Hong ("**Dr. Hong**") as the chairman of the Board and the chief executive officer of the Company deviates from the relevant code provision. Dr. Hong, as the founder of the Group, has extensive experience in the biopharmaceutical industry and has served in the Company since its establishment. Dr. Hong is in charge of overall management, business, strategic development and scientific 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 authority and control is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises two executive Directors, one non-executive Director and five independent non-executive Directors, and therefore has a strong independent element in its composition. The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairman and the chief executive officer is necessary.

# MODEL CODE FOR SECURITIES TRANSACTIONS

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

#### PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

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

# 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, 2022), and is of the view that the annual results of the Group for the year ended December 31, 2022 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, 2022 as set out in this preliminary announcement have been agreed by the Group's 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 24, 2023. 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 the preliminary announcement.

# 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, 2022 containing all the information required by the Listing Rules will be dispatched 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 20, 2023
"AIDS"	acquired immunodeficiency syndrome, defined as an HIV infection with either a CD4+ T-cell count below 200 cells per $\mu$ 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)
"APASL"	the Asian Pacific Association for the Study of Liver
"ART"	antiretroviral therapy
"Audit and Risk Committee"	the audit and risk committee of the Board
"BLA"	biologics license application
"BLI"	β-lactamase inhibitor
"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 14 to the Listing Rules
"China" or "the PRC"	the People's Republic of China excluding, for the purposes of this announcement, Hong Kong, the Macau Special Administrative Region of the People's Republic of China and Taiwan
"СМО"	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", "Our 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
"COVID-19"	Coronavirus Disease 2019, a disease caused by the novel virus 2 SARS-CoV-2 and designated as severe acute respiratory syndrome
"CRO"	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
"Director(s)"	director(s) of the Company
"DNA"	deoxyribonucleic acid
"EFdA" or "islatravir"	an NRTTI and an investigational drug for the treatment of HIV infection
"ESG"	environmental, social and governance
"EUA"	Emergency Use Authorization
"FVTPL"	fair value loss on financial liabilities at fair value through profit or loss
"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
"HIV"	human immunodeficiency virus
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"HK\$"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"IDWeek"	Infectious Disease Week
"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
"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 10 to the Listing Rules
"MDD"	major depressive disorders
"MDR/XDR"	multi-drug resistant/extensive drug resistant
"MRCT"	the multi-regional clinical trials
"MSCI"	MSCI Inc., an American finance company
"NCE"	new chemical entity
"NDA"	new drug application
"NMPA"	The National Medical Products Administration
"NNRTI"	non-nucleoside reverse transcriptase inhibitor, a form of ART used to treat HIV infection or AIDS

"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 mycobacterial
"PEG-IFN-α"	pegylated interferon alfa
"РК"	pharmacokinetics
"POC"	proof of concept
"PPD"	postpartum depression
"Prospectus"	the prospectus of the Company dated June 30, 2021
"QIDP"	Qualified Infectious Disease Product
"Qpex"	Qpex Biopharma Inc., a corporation incorporated in Delaware, United States
"Reporting Period"	the year ended December 31, 2022
"RMB"	Renminbi, the lawful currency of the PRC
"RNA"	ribonucleic acid
"R&D"	research and development
"SAD/MAD"	single ascending dose and multiple ascending dose
"SARS-CoV-2"	severe acute respiratory syndrome coronavirus 2
"Share(s)"	ordinary share(s) in the share capital of the Company with a nominal value of US\$0.00001 each
"Shareholder(s)"	the holder(s) of the Share(s)
"siRNA"	small interfering RNA, sometimes known as short interfering RNA or silencing RNA, a class of double stranded non-coding RNA molecules
"Strategy Committee"	the Strategy Committee of the Board
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"TSB Therapeutics"	TSB Therapeutics Ltd (Beijing) Co. Limited, a limited liability company incorporated in the PRC, being an indirect non-wholly owned subsidiary of our Company

"United States" or "U.S." or "USA"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US\$" or "USD"	United States dollars, the lawful currency of the United States
"U.S. FDA"	the U.S. Food and Drug Administration
"VBI"	VBI Vaccines Inc., a corporation with corporate headquarters in Cambridge, the United States, whose stocks are listed on the NASDAQ Global Market (NASDAQ: VBIV)
"Vir"	Vir Biotechnology, Inc., a corporation incorporated in San Francisco, the United States, whose stocks are listed on the NASDAQ Global Market (NASDAQ: VIR)
"%"	per cent.
	By order of the Board

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

Hong Kong, March 24, 2023

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