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Brii Biosciences Limited
騰盛博药生物科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2137)

INTERIM RESULTS ANNOUNCEMENT
FOR THE SIX MONTHS ENDED JUNE 30, 2022

The Board of Brii Biosciences Limited is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2022, together with the comparative figures for the previous year.

FINANCIAL HIGHLIGHTS

- Other income was RMB38.2 million for the six months ended June 30, 2022, representing a decrease of RMB8.1 million or 17.4%, compared with RMB46.3 million for the six months ended June 30, 2021. The decrease was mainly due to the decrease in income recognized from PRC government grants of RMB17.8 million. The decrease was partially offset by the increase in bank interest income of RMB9.7 million attributable to the increased bank and cash balances after the Global Offering.
- R&D expenses were RMB258.5 million for the six months ended June 30, 2022, representing an increase of RMB100.9 million or 64.0%, compared with RMB157.6 million for the six months ended June 30, 2021. The increase was primarily due to the increase in third party contracting fees, as well as the employee cost, for our continuous development in clinical trials.
- Administrative expenses were RMB95.5 million for the six months ended June 30, 2022, representing an increase of RMB27.5 million or 40.4%, compared with RMB68.0 million for the six months ended June 30, 2021. The increase was primarily attributable to the increase in employee headcount, as well as the increase in stock compensation expense for employees.
- We established a streamlined commercial team to better support the launch and distribution of amubarvimab/romlusevimab combination therapy. As a result, we started to incur selling and marketing expenses, which primarily consist of employee related costs and pre-launch activity expenses.
- Total comprehensive expense for the six months ended June 30, 2022 was RMB217.7 million, representing a decrease of RMB2,703.8 million or 92.5%, compared with RMB2,921.5 million for the six months ended June 30, 2021. The decrease was primarily due to the decrease in fair value loss on financial liabilities at FVTPL.

BUSINESS HIGHLIGHTS

Since the Company's founding in 2017, we have been dedicated to alleviating global public health burdens, with focus on advancing therapies for significant infectious diseases and central nervous system disorders. Our international teams in China and the U.S. are committed to and adept at collaborating in ways that maximize our collective strengths and various areas of expertise in both key markets, as well as other areas around the world. 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. This unique global approach has produced a robust and dynamic pipeline of promising therapeutic candidates and a number of other remarkable achievements. In July 2022, we successfully transitioned from the clinical development stage to a commercial stage with the launch of our first product: long-acting amubarvimab/romlusevimab combination therapy for COVID-19 in China.

In support of our commercial progress and as our programs advance through clinical development, we have expanded the depth and breadth of our corporate executive leadership team to guide our public-health inspired programs as at the date of this announcement. Bringing us professional experience in their respective fields, Dr. Susannah Cantrell, Ph.D., has joined the Company as our Chief Business Officer, Dr. Eleanor (Ellee) de Groot was appointed as our Senior Vice President, Chief Technology Officer, Ms. Karen D. Neuendorff was appointed as our Chief People Officer and Dr. Aleksandar Skuban joined the Company as our Vice President, Head of Neurosciences Therapy Area. Together, our team is working to deliver positive impact for patients, public health and society as we invest in medicines that have the potential to make a profound difference in many people's lives.

As at the date of this announcement, we have established a diversified pipeline with more than 10 product candidates that are mostly under clinical development, relying on our in-house team with strong product discovery and translational research capabilities and our extensive partnership with industry leaders around the globe. In search of viable treatments, in China, our focus is on HBV, COVID-19 and MDR/XDR, where we advance our programs through in-house R&D and with our partners. In the U.S., we mainly focus on our internally discovered HIV and anti-depression program.

Driven by our unique combination therapy design based on RNA interference therapeutics, we aim to be the first company to find an HBV functional cure. China accounts for the world's largest HBV population, where we have the most advanced clinical development program with a robust portfolio of HBV assets that we are evaluating primarily as combination therapies. Most recently, in July 2022, we further strengthened our core HBV assets by exercising our option to in-license BR11-877 (VIR-3434) from our partner Vir, a strong HBV-neutralizing monoclonal antibody, which we have rights to develop and commercialize it in the Greater China area. As at the date of this announcement, we are conducting two ongoing Phase 2 combination trials in China for HBV for which we expect to deliver new data later this year.

For our COVID-19 program, after the successful commercial launch in July 2022, our long-acting amubarvimab/romlusevimab combination therapy has been delivered to places suffering from the epidemic across China. Given the rapid evolution of the virus mutation and new variants, an effective neutralizing antibodies combination is still in need as a supplement to vaccination, especially to patients with compromised immunity. In July 2022, the live virus data confirmed that our long-acting amubarvimab/romlusevimab combination therapy retains neutralizing activity against Omicron BA.4/5 and BA.2.12.1 subvariants which are dominant in most of the areas around the world. The amubarvimab/romlusevimab combination is one of the very few neutralizing antibodies that continue to show neutralizing activities in all current variants of concern. The U.S. FDA is currently reviewing the Company's Emergency Use Authorization application for the amubarvimab/romlusevimab combination.

As at the date of this announcement, in addition to the programs developed in China, our self-developed programs in the U.S. also made progress. For the HIV program, we have received an initial response from the U.S. FDA outlining the requirements for the release of the clinical hold and further clarification is ongoing. We are working closely with the U.S. FDA to align on our understanding of the safety signal identified in the islatravir-related studies. Our aim is to lift the clinical hold as soon as we can in 2022 and proceed with the development of our once-weekly oral combination of BRII-732 and BRII-778.

In our CNS therapeutic area, we continued to build our team of industry leaders across the business and execute our strategy to explore the treatment and prevention of post-partum depression with BRII-296, as well as the treatment for various anxiety and depressive disorders with BRII-297. We aim to initiate the Phase 1 study of BRII-297 in the fourth quarter of 2022.

In addition to our treatment of COVID-19, as well as our ongoing clinical trials focused on HBV, HIV and with our CNS program, we hold the Greater China rights to therapeutic candidates for the treatment of multidrug resistant and extensively drug resistant gram-negative infections and TB mycobacteria and nontuberculosis mycobacteria programs, which are under clinical development by our partners Qpex and AN2, respectively.

As our innovation is driven by patient insight, the Company has made great efforts to engage in patient centricity programs. As at the date of this announcement, we sponsored 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. These types of events would foster relationships with patients, their caregivers, and the disease-specific nonprofit groups that support them. We believe, it will ensure patients' voices are understood across every function, from R&D to commercialization.

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

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

Major Milestones Achieved As At the Date of This Announcement

Hepatitis B Virus Functional Cure Program (*China team core project*)

- ***BRII-179 (VBI-2601) and BRII-835 (VIR-2218) (therapeutic vaccine and siRNA) Combination***
 - o In February 2022, we completed the enrollment of 90 patients from the Asia-Pacific region in our Phase 2 MRCT combination study.

- ***BRII-179 (VBI-2601) and PEG-IFN- α combination therapy***
 - o A two-part Phase 2a/2b combination study with BRII-179 (VBI-2601) in HBV patients receiving PEG-IFN- α and NRTI treatment is currently recruiting patients in China.
- ***BRII-835 (VIR-2218)***
 - o In March 2022, we presented findings from the Phase 2 China study on the safety and antiviral activity of BRII-835 (VIR-2218) administered on top of nucleos(t)ide analog therapy at the 2022 Asian Pacific Association for the Study of the Liver conference. The dose-dependent reduction in serum HBsAg observed in both HBeAg- and HBeAg+ Chinese chronic HBV patients in this trial after two doses of BRII-835 (VIR-2218) is consistent with previous findings demonstrated in other racial/ethnic groups.
 - o Our partner Vir presented data at the International Liver Congress in June 2022, showing longer treatment duration of monthly BRII-835 (VIR-2218) results in deeper and more sustained reductions in HBsAg in participants with chronic HBV infection.
- ***BRII-877 (VIR-3434) (Study conducted by Vir)***
 - o Data from a Phase 1 monotherapy study led by Vir were presented at the International Liver Congress in June 2022 demonstrating the dose-dependent durability of HBsAg reductions following administration of a single dose of BRII-877 (VIR-3434).
 - o 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 its broader collaboration with Vir.
- ***BRII-835 (VIR-2218) and BRII-877 (VIR-3434) (siRNA and antibody combination conducted by Vir)***
 - o Our partner, Vir, shared encouraging data from Part A of its Phase 2 MARCH study in April 2022, which suggest that BRII-835 (VIR-2218) and BRII-877 (VIR-3434) are additive in reducing HBsAg, with no drug-related safety signals reported to date. Vir expects additional data from Part A later this year.

COVID-19 Program (*Internally discovered. China team core project*)

- Amubarvimab/romlusevimab combination therapy (formerly BRII-196 and BRII-198 combination therapy)
 - o We completed a Phase 2 study of amubarvimab/romlusevimab combination therapy (formerly BRII-196 and BRII-198 combination therapy) led by Prof. Nanshan Zhong as the lead principal investigator. Data demonstrated that the combination therapy is generally safe and well-tolerated in both severe and non-severe Chinese patients with COVID-19. Favorable efficacy profiles were observed, consistent with the results observed in the ACTIV-2 study.

- o As COVID-19 continues to evolve, we completed a neutralization activity evaluation on Omicron variants using pseudo Virus-Like Particles expressing the full-length spike protein of Omicron subvariants and available authentic Omicron viruses. The testing data from multiple independent laboratories demonstrate that the Company's long-acting amubarvimab/romlusevimab combination retains neutralizing activity against all previous variants of concern and Omicron subvariants, including the following commonly identified ones, 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 (Omicron), as well as Omicron subvariants BA.1.1, BA.2, BA.2.12.1 and BA.4/5.
- o The long-acting amubarvimab/romlusevimab combination therapy was added to the COVID-19 Diagnosis and Treatment Guidelines (9th Pilot Edition) in March 2022 by the National Health Commission of China.
- o The long-acting amubarvimab/romlusevimab combination therapy was commercially launched in China in July 2022 following the completion of the GMP compliance inspections.
- o We announced strategic partnerships with Sinopharm Group and CR Pharma Comm in March and July 2022, respectively, to advance the commercialization of our long-acting COVID-19 neutralization antibody therapy in China.
- o The U.S. FDA is currently reviewing our Emergency Use Authorization application for the amubarvimab/romlusevimab combination.
- o An investigator-initiated randomized, double-blind and placebo-controlled Phase 2 study is planned by the First Affiliated Hospital of Guangzhou Medical University, aiming at evaluating the level of enhanced SARS-CoV-2 specific immunity after single infusion of amubarvimab/romlusevimab combination in immunocompromised population.

Central Nervous System Disease Program (*Internally discovered. U.S. team core project*)

• ***BR11-296***

- o Our Phase 1 SAD study for BR11-296 is ongoing and we have requested a Type C meeting with the U.S. FDA to align on our clinical development plan for both PPD treatment and prevention.

• ***BR11-297***

- o We are conducting IND-enabling studies with BR11-297 targeting various anxiety and depression disorders.

HIV Program (*Internally discovered. U.S. team core project*)

- ***BRII-778***
 - We completed the final clinical study report for our BRII-778 Phase 1 SAD/MAD trial in June 2022.
- ***BRII-732***
 - We completed our Phase 1 SAD/MAD study of BRII-732 in May 2022.
 - We have received an initial response from the U.S. FDA outlining the requirements for release of the clinical hold and further clarification is ongoing. We are working closely with the agency to align on our understanding of the safety signal identified in the islatravir related studies.

MDR/XDR Gram-negative Infections Program (*China team core project*)

We are developing our MDR/XDR therapies in collaboration with our partner Qpex as part of its global development plan. We retain responsibility for the development and filing activities in Greater China, while Qpex is responsible for all development and regulatory activities outside Greater China.

- ***BRII-636 (OMNIvance®)***
 - In early 2022, our partner Qpex announced that BRII-636 (INN: xeruborbactam) in combination with a non-disclosed IV beta-lactam antibiotic received QIDP designation by the U.S. FDA.
 - Qpex has completed enrollment in a first-in-human Phase 1 study and a drug-drug interaction study.
- ***BRII-672 (ORAvance™)***
 - 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, and its Phase 1 study is progressing and on track to be completed.
- ***BRII-693 (QPX-9003)***
 - Qpex announced in early 2022 that BRII-693 received QIDP designation by the U.S. FDA.
 - Enrollment in the first-in-human Phase 1 clinical study has been completed, including a cohort of Chinese subjects.

MDR/XDR Mycobacterium Tuberculosis and Nontuberculosis Mycobacteria Program (China team core project)

Our partner, AN2, is developing eptraborole as a once-daily, orally administered treatment for patients with chronic NTM lung disease in the U.S., with an initial focus on treatment-refractory MAC lung disease.

- ***BR11-658 (epetraborole)***
 - In June 2022, AN2 initiated patient enrollment for a pivotal Phase 2/3 clinical trial for treatment-refractory MAC lung disease.

Other Corporate Developments

- We expanded our diverse global executive team with the additions of Dr. Susannah Cantrell as our Chief Business Officer, Dr. Eleanor (Ellee) de Groot as our Senior Vice President, Chief Technology Officer and Dr. Aleksandar Skuban as our Vice President, CNS Disease Therapy Area Head. Also, Ms. Karen D. Neuendorff was appointed as our Chief People Officer early this year. Each of these accomplished industry executives boasts a strong track record of success in leading international teams.
- In July 2022, we announced the exercise of the option to acquire exclusive development and commercialization rights for VIR-3434 in Greater China as part of our broader collaboration with Vir Biotechnology, Inc. This move provides additional growth to the Company's leading clinical pipeline of therapeutic candidates for HBV and provides an expansive set of potential combination treatment options for the Company to explore as part of its efforts to develop a functional cure for HBV.
- 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 sponsored 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. These types of events would foster relationships with patients, their caregivers, and the disease-specific nonprofit groups that support them. We believe, it will ensure patients' voices are better understood across every function, from R&D to commercialization.

For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the Company's prior announcements published on the websites of the Stock Exchange and the Company.

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

For the six months ended June 30, 2022

		Six months ended	
		June 30, 2022	June 30, 2021
	<i>Notes</i>	RMB'000 (unaudited)	RMB'000 (unaudited)
Other income	4	38,228	46,280
Other gains and losses		(34,035)	(9)
Research and development expenses		(258,484)	(157,611)
Administrative expenses		(95,467)	(67,990)
Selling and marketing expenses		(15,376)	–
Fair value loss on financial liabilities at fair value through profit or loss (“FVTPL”)		–	(2,751,575)
Finance costs		(480)	(893)
Listing expenses		–	(21,781)
Loss before tax	5	(365,614)	(2,953,579)
Income tax expense	6	–	–
Loss for the period		(365,614)	(2,953,579)
Other comprehensive income (expense):			
<i>Items that will not be reclassified to profit or loss:</i>			
Exchange differences on translation from functional currency to presentation currency		173,492	25,158
Fair value (loss) gain on equity instrument at fair value through other comprehensive income (“FVTOCI”)		(22,780)	8,918
		150,712	34,076
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences arising on translation of foreign operations		(2,785)	(1,953)
Other comprehensive income for the period		147,927	32,123
Total comprehensive expense for the period		(217,687)	(2,921,456)
Loss for the period attributable to:			
Owners of the Company		(347,587)	(2,953,177)
Non-controlling interests		(18,027)	(402)
		(365,614)	(2,953,579)
Total comprehensive expense for the period attributable to:			
Owners of the Company		(199,660)	(2,921,054)
Non-controlling interests		(18,027)	(402)
		(217,687)	(2,921,456)
Loss per share			
Basic and diluted (RMB)	7	(0.48)	(14.86)

UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

At June 30, 2022

	Notes	At June 30, 2022 RMB'000 (unaudited)	At December 31, 2021 RMB'000 (audited)
Non-current assets			
Property, plant and equipment		9,959	12,573
Right-of-use assets		16,520	20,862
Intangible assets		8,148	9,506
Financial assets at FVTPL		128,946	117,790
Equity instrument at FVTOCI		12,477	34,241
Rental deposits	9	2,786	2,786
		<u>178,836</u>	<u>197,758</u>
Current assets			
Deposits, prepayments and other receivables	9	71,031	58,882
Restricted bank deposits		2,474	319
Time deposits with original maturity over three months		253,276	499,647
Bank balances and cash		2,966,195	2,855,093
		<u>3,292,976</u>	<u>3,413,941</u>
Current liabilities			
Other payables	10	271,241	218,860
Lease liabilities		9,267	8,969
Deferred income		27,840	52,884
		<u>308,348</u>	<u>280,713</u>
Net current assets		<u>2,984,628</u>	<u>3,133,228</u>
Total assets less current liabilities		<u>3,163,464</u>	<u>3,330,986</u>
Non-current liabilities			
Lease liabilities		8,204	12,647
Deferred income		4,583	7,083
		<u>12,787</u>	<u>19,730</u>
Net assets		<u>3,150,677</u>	<u>3,311,256</u>
Capital and reserves			
Share capital		23	23
Share premium and reserves		3,200,329	3,342,881
Equity attributable to owners of the Company		3,200,352	3,342,904
Non-controlling interests		(49,675)	(31,648)
Total equity		<u>3,150,677</u>	<u>3,311,256</u>

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 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, Uglan 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 condensed consolidated financial statements is RMB as it best suits the needs of the shareholders and investors.

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

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

2. PRINCIPAL ACCOUNTING POLICIES

These condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments which are measured at fair value at the end of each reporting period.

Other than additional accounting policies resulting from application of amendments to International Financial Reporting Standards (“IFRSs”), the accounting policies and methods of computation used in these condensed consolidated financial statements for the six months ended June 30, 2022 are the same as those presented in the Group’s annual financial statements for the year ended December 31, 2021.

Application of amendments to IFRSs

In the current interim period, the Group has applied the following amendments to IFRSs issued by the IASB, for the first time, which are mandatorily effective for the annual periods beginning on or after January 1, 2022 for the preparation of the Group’s condensed consolidated financial statements:

Amendments to IFRS 3	Reference to the Conceptual Framework
Amendments to IFRS 16	Covid-19-Related Rent Concessions beyond 30 June 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 IFRS Standards	Annual Improvements to IFRS Standards 2018-2020

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

3. SEGMENT INFORMATION

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

Geographical information

All of the Group's non-current assets (excluding financial instruments) are located in the PRC.

4. OTHER INCOME

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Government grants (<i>Note</i>)	27,885	45,660
Bank interest income	10,343	620
	<u>38,228</u>	<u>46,280</u>

Note: Government grants include the incentive and other subsidies from the PRC government which are specifically for R&D activities, and are recognized upon compliance with the attached conditions. In the current interim period, the Group did not (six months ended June 30, 2021: nil) receive any government grants. At June 30, 2022, government grants of RMB32.4 million (December 31, 2021: RMB60.0 million) have not fully reached the relevant conditions and therefore these government grants were deferred and recorded as deferred income.

5. LOSS BEFORE TAX

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Loss before tax for the period has been arrived at after charging:		
Depreciation of property, plant and equipment	2,614	2,415
Depreciation of right-of-use assets	4,342	4,222
Amortization of intangible assets (included in R&D expenses)	1,358	1,358
	<u>8,314</u>	<u>7,995</u>

6. INCOME TAX EXPENSE

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

7. LOSS PER SHARE

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

	Six months ended June 30,	
	2022	2021
	(unaudited)	(unaudited)
Loss for the period attributable to the owners of the Company for the purpose of basic and diluted loss per share (<i>RMB '000</i>)	<u>(347,587)</u>	<u>(2,953,177)</u>
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share (<i>'000</i>)	<u>721,780</u>	<u>198,737</u>

The computation of basic and diluted loss per share for the six months ended June 30, 2021 and 2022 excluded the unvested restricted ordinary shares of the Company.

The computation of diluted loss per share for the six months ended June 30, 2022 did not assume the exercise of share options, the vesting of restricted share units and the vesting of restricted ordinary shares since their assumed exercise and vesting would result in a decrease in loss per share.

The weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share has been determined on the assumption that share subdivision has been effective on January 1, 2021.

The computation of diluted loss per share for the six months ended June 30, 2021 did not assume conversion of the preferred shares, the exercise of share options and the vesting of restricted ordinary shares since their assumed conversion, exercise and vesting would result in a decrease in loss per share.

8. DIVIDENDS

No dividend was paid or declared by the Company during the six months ended June 30, 2022.

9. RENTAL DEPOSITS/DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

	At June 30, 2022 RMB '000 (unaudited)	At December 31, 2021 <i>RMB '000</i> (audited)
Value-added tax recoverable	52,089	45,537
Prepayments	11,114	7,365
Interests receivable	5,625	4,873
Rental and other deposits	2,786	2,786
Other receivables	<u>2,203</u>	<u>1,107</u>
	<u>73,817</u>	<u>61,668</u>
Analyzed as:		
Non-current	2,786	2,786
Current	<u>71,031</u>	<u>58,882</u>
	<u>73,817</u>	<u>61,668</u>

10. OTHER PAYABLES

	At June 30, 2022 <i>RMB'000</i> (unaudited)	At December 31, 2021 <i>RMB'000</i> (audited)
Payables for research and development expenses	202,822	44,111
Accrued research and development expenses	34,074	136,835
Payroll payables	19,862	23,840
Accrued issue costs	10,738	10,201
Other tax payables	1,284	1,653
Other payables for		
– legal and professional fee	1,384	1,042
– others	1,077	1,178
	<u>271,241</u>	<u>218,860</u>

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

	At June 30, 2022 <i>RMB'000</i> (unaudited)	At December 31, 2021 <i>RMB'000</i> (audited)
0-30 days	39,247	43,327
31-60 days	10,387	780
61-90 days	144,161	4
Over 90 days	9,027	–
	<u>202,822</u>	<u>44,111</u>

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 has moved to the next stage of development, our global leadership team has been expanded with diversified talent with extensive expertise. Early this year, Ms. Karen D. Neuendorff was appointed as our Chief People Officer to foster people-centric HR initiatives within the Company. In July 2022, Dr. Susannah Cantrell joined the Company as the Chief Business Officer. As we expand our public health-inspired programs, we're excited to leverage her 20 years of healthcare and biotechnology industry experience spanning our global pipeline strategy, sales, operations, marketing, and new product commercialization. This month, we also welcomed Dr. Eleanor (Ellee) de Groot as our Senior Vice President, Chief Technology Officer and Dr. Aleksandar Skuban joined us as Vice President, CNS Disease Therapy Area Head, as we take a deeper dive into our important CNS program that focuses on mental health with initial indications in postpartum depression and major depressive disorder.

With these new additions to our leadership team, 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 recently launched for commercial availability our long-acting antibody combination therapy for COVID-19 in China. In the U.S., we are centered on our internally discovered CNS and HIV programs, leveraging our strong in-house R&D capabilities.

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 BR11-877, 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.

In response to the unprecedented global COVID-19 pandemic, and consistent with our commitment to tackle public health challenges, we have developed a long-acting neutralizing antibody cocktail therapy for the treatment of COVID-19. Following regulatory approval in December 2021, we successfully launched commercially our neutralizing antibodies in July 2022 with the first batch dispatch and dose prescription. By working closely with the leading distributor enterprises in China, we further strengthen and advance the near- and long-term commercialization process with extensive drug marketing, national distribution channel network, and comprehensive hospital access.

In response to the global HIV pandemic, we discovered and are developing a long-acting, once-weekly single tablet regimen for HIV patients with an initial focus in the U.S. We have received an initial response from the U.S. FDA outlining the requirements for release of the clinical hold and further clarification is ongoing.

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 continued development in China.

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 the first half of 2022, we continued to build our internal discovery team to progress BRII-296 for the treatment and prevention of postpartum depression, as well as BRII-297 for the treatment of various anxiety and depression disorders. We aim to initiate the Phase 1 study for BRII-297 in the fourth quarter of 2022.

Having quickly pivoted in 2020 and 2021 to serve the greater global needs compelled by COVID-19 and its variants, we were able to rapidly move through the clinical and regulatory processes to obtaining BLA approval and a commercial launch in 27 months. Next, we will carry forward the experience from our COVID-19 program to expand and advance our other public health-inspired clinical programs with the goal of bringing proven and meaningful long-term therapeutic solutions to patients and the healthcare community. In light of our strategic priorities for the second half 2022, we are dedicated to:

- o Advancing BRII-179 (VBI-2601) and BRII-835 (VIR-2218) combination (therapeutic vaccine and siRNA combination therapy) and BRII-179 (VBI-2601) with PEG-IFN- α (therapeutic vaccine in HBV patients receiving PEG-IFN- α and NRTI treatment) to provide functional cures for HBV infection in the Greater China;
- o Under the lead of our newly joined CNS Disease Therapy Area Head, further advancing the clinical development of BRII-296 for the treatment and prevention of postpartum depression, as well as BRII-297 for the treatment of various anxiety and depression disorders;
- o Ensuring sufficient supply of long-acting amubarvimab/romlusevimab antibodies for commercialization, and extend our product accessibility in other countries;
- o Expanding our pipeline through in-house discovery and additional licensing options. 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 United States to support our developing business 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 mental illnesses. 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	Regulatory Authority	Brii Rights	Partners	
Infectious Disease Programs											
Hepatitis B	BRII-179 (VBI-2601)/BRII-835 (VIR-2218) Combination	[Progress bar: Preclinical to Phase 2]							NMPA	Greater China	YBI VIR
	BRII-179 (VBI-2601)/PEG-IFN- α Combination	[Progress bar: Preclinical to Phase 2]							NMPA	Greater China	VBI
	BRII-877 (VIR-3434) ⁽¹⁾	[Progress bar: Preclinical to Phase 2]							NMPA	Greater China	VIR
COVID-19	Amubarvimab/romlusevimab Combination ⁽²⁾ (previously BRII-196/BRII-198)	[Progress bar: Preclinical to Phase 2]					China BLA approved and commercial launched		NMPA/FDA	Global	[Logos]
HIV infection	BRII-778	[Progress bar: Preclinical to Phase 1]							FDA	Global	Internally discovered
	BRII-732 ⁽³⁾	[Progress bar: Preclinical to Phase 1]							FDA	Global	Internally discovered
MDR/XDR gram-negative infections	BRII-636 ⁽⁴⁾ (OMNivance [®])	[Progress bar: Preclinical to Phase 1]							FDA	Greater China	QPEX
	BRII-672 ⁽⁴⁾ (ORAvance [™])	[Progress bar: Preclinical to Phase 1]							FDA	Greater China	QPEX
	BRII-693 ⁽⁴⁾ (QPX-9003)	[Progress bar: Preclinical to Phase 1]							FDA	Greater China	QPEX
Nontuberculosis mycobacteria	BRII-658 ⁽⁴⁾ (Epetraborole)	[Progress bar: Preclinical to Phase 1]							FDA	Greater China	AN2 Therapeutics
Central Nervous System Disease Programs											
PPD	BRII-296	[Progress bar: Preclinical to Phase 1]							FDA	Global	Internally discovered
PPD prevention	BRII-296	[Progress bar: Preclinical to Phase 1]							FDA	Global	Internally discovered
Anxiety and depressive disorder	BRII-297	[Progress bar: Preclinical to Phase 1]							FDA	Global	Internally discovered

Notes:

1. The Phase 2 clinical trials have been conducted by Vir.
2. The filing of EUA application with the U.S. FDA for combination amubarvimab/romlusevimab has been completed in December 2021.
3. Phase 1 study of BRII-732 is currently on clinical hold as part of the U.S. FDA's decision to temporarily hold islatravir-based clinical studies.
4. To this date, the development and clinical trials have been conducted by Qpex and AN2, respectively.

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 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);
- o BRII-778 and BRII-732 for the treatment of HIV;
- o BRII-296 for the treatment of PPD/MDD; and
- o BRII-297 for the treatment of various anxiety and depressive disorders.

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 MDR/XDR TB and NTM, with an initial focus on treatment of treatment-refractory Mycobacterium avium complex lung disease.

BUSINESS REVIEW

During the first half of 2022, we rapidly advanced our product pipeline and business operations. Specifically, we launched our first commercial product in China for COVID-19, and advanced our programs for HBV, HIV, MDR/XDR gram-negative or NTM infections, and PPD/MDD or other anxiety and depressive disorders, as well as broadened the depth of our senior executive leadership team. Our primary achievements as at 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 Vaccines Inc. and Vir Biotechnology, Inc. China team core project)

To treat HBV, we are currently developing BRII-179 (VBI-2601), an HBV-specific B cell and T cell immunotherapeutic vaccine candidate, and BRII-835 (VIR-2218), an investigational HBV targeting siRNA, that have the potential to stimulate an effective immune response and have direct antiviral activity against HBV. We hold exclusive rights to develop and commercialize BRII-179 (VBI-2601), BRII-835 (VIR-2218) and BRII-877 (VIR-3434) in Greater China. As a potential HBV functional cure regimen, we are focusing on developing BRII-179 (VBI-2601) and BRII-835 (VIR-2218) as a combination therapy.

Combination of BRII-179 (VBI-2601) and BRII-835 (VIR-2218) for HBV Functional Cure

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 2022, we completed the enrollment of 90 patients from the Asia-Pacific region in our Phase 2 multi-regional clinical trial combination study of BRII-179 (VBI-2601)/BRII-835 (VIR-2218).

Next Achievements and Upcoming Readouts

- Patients are expected to complete treatment in the Phase 2 MRCT combination therapy study in the third quarter of 2022, with interim topline data expected by the end of 2022.
- If positive results are achieved in the combination study, we plan to initiate pre-IND discussion with CDE in 2023 for a pivotal study.

BRII-179 (VBI-2601) and PEG-IFN- α combination therapy for HBV patients receiving NRTI treatment

BRII-179 (VBI-2601): As one of our most advanced therapeutic candidates, BRII-179 (VBI-2601) is a novel recombinant protein-based HBV immunotherapeutic candidate. We in-licensed rights to BRII-179 (VBI-2601) in Greater China from VBI in December 2018. This therapeutic vaccine candidate builds upon the 3-antigen conformation of VBI's prophylactic HBV vaccine candidate with a Th-1 enhancing adjuvant to induce both B-cell and T-cell immune responses.

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

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

- Continued enrolling patients in Phase 2a of our Phase 2 combination study containing two parts. Phase 2a is designed to determine the efficacy and safety of BRII-179 (VBI-2601) therapy in approximately 120 patients in combination with PEG-IFN- α + NRTI therapy. In Phase 2b, the study will expand to 480 patients to evaluate the proportion of patients achieving functional cure, defined as undetectable HBsAg and sustained suppression of HBV DNA, after receiving BRII-179 (VBI-2601) therapy in combination with PEG-IFN- α + NRTI.

Next Achievements and Upcoming Readouts

- Patient enrollment for part 1 (Phase 2a of approximately 120 patients) of the study is expected to be completed in the fourth quarter of 2022.
- Topline data readout is planned in the first half of 2023.

BRII-835 (VIR-2218): BRII-835 (VIR-2218) is an investigational, subcutaneously administered HBV-targeting siRNA that has the potential to stimulate an effective immune response and has direct antiviral activity against HBV. It is the first siRNA in the clinic to include Enhanced Stabilization Chemistry Plus technology to enhance stability and minimize off-target activity, which potentially can result in an increased therapeutic index.

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

- In March 2022, we presented findings from the Phase 2 China study on the safety and antiviral activity of BRII-835 (VIR-2218) administered on top of nucleos(t)ide analog therapy at the 2022 Asian Pacific Association for the Study of the Liver conference. The dose-dependent reduction in serum HBsAg observed in both HBeAg- and HBeAg+ Chinese chronic HBV patients in this trial after two doses of BRII-835 (VIR-2218) is consistent with previous findings demonstrated in other racial/ethnic groups.
- Our partner, Vir presented data at the International Liver Congress in June 2022, showing longer treatment duration of monthly BRII-835 (VIR-2218) results in deeper and more sustained reductions in HBsAg in participants with chronic HBV infection.

Next Achievements and Upcoming Readouts

- Additional data from the Phase 2 study of BRII-835 (VIR-2218) in combination with PEG-IFN- α led by Vir are expected in the second half of 2022.

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

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

- Data from a Phase 1 monotherapy study led by Vir were presented at the International Liver Congress in June 2022 demonstrating the dose-dependent durability of HBsAg reductions following administration of a single dose of BRII-877 (VIR-3434).
- In virally suppressed participants with HBsAg of less than 3,000 IU/mL, a single 6 mg to 75 mg dose of BRII-877 (VIR-3434) resulted in rapid HBsAg reductions of greater than 1 log₁₀ IU/mL in most participants. Single dose of BRII-877 (VIR-3434) showed no clinically significant safety signals; all adverse events were Grade 1 or 2. These data support the potential for BRII-877 (VIR-3434) to provide a meaningful role in the functional cure of chronic HBV infection.
- 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.

Next Achievements and Upcoming Readouts

- We plan to request a pre-IND meeting with China's CDE for a Phase 1 study of BRII-877 (VIR-3434) by the end of 2022.

BRII-835 (VIR-2218) and BRII-877 (VIR-3434) Combination

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

- Our partner, Vir, shared encouraging data from Part A of its Phase 2 MARCH study in April 2022, which suggest that BRII-835 (VIR-2218) and BRII-877 (VIR-3434) are additive in reducing HBsAg, with no drug-related safety signals reported to date.

Next Achievements and Upcoming Readouts

- Additional data from the first cohort (Part A) of the Phase 2 MARCH study evaluating safety, pharmacokinetics and HBsAg suppression of BRII-835 (VIR-2218) and BRII-877 (VIR-3434) combination are expected later this year.
- Part B of the Phase 2 MARCH trial initiated in the second quarter of 2022 will evaluate additional cohorts to determine dose and length of treatment, and evaluate triple cocktails with PEG-IFN- α , when BRII-877 (VIR-3434) is given every 4 weeks.

COVID-19 Program (Discovered in collaboration with Tsinghua University and Third People's Hospital of Shenzhen through our subsidiary, TSB Therapeutics. China team core project)

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 a conditional approval. In March 2022, the National Health Commission of China included the amubarvimab/romlusevimab combination in its COVID-19 Diagnosis and Treatment Guidelines (9th Pilot Edition) for the treatment of COVID-19.

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

- We completed a Phase 2 study of amubarvimab/romlusevimab combination therapy (formerly BRII-196 and BRII-198 combination therapy) led by Prof. Nanshan Zhong as the lead principal investigator. Data demonstrated that the combination therapy is generally safe and well-tolerated in both severe and non-severe Chinese patients with COVID-19. Favorable efficacy profiles were observed, consistent with the results observed in the ACTIV-2 study.

- As COVID-19 continues to evolve, we completed a neutralization activity evaluation on Omicron variants using pseudo Virus-Like Particles expressing the full-length spike protein of Omicron subvariants and available authentic Omicron viruses. The testing data from multiple independent laboratories demonstrate that the Company's long-acting amubarvimab/romlusevimab combination retains neutralizing activity against all previous variants of concern and Omicron subvariants, including the following commonly identified ones, 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 (Omicron), as well as Omicron subvariants BA.1.1, BA.2, BA.2.12.1 and BA.4/5.
- The long-acting amubarvimab/romlusevimab combination therapy was added to the COVID-19 Diagnosis and Treatment Guidelines (9th Pilot Edition) in March 2022 by the National Health Commission of China.
- The long-acting amubarvimab/romlusevimab combination therapy was commercially launched in China in July 2022 following the completion of the GMP compliance inspections.
- We announced strategic partnerships with Sinopharm Group and CR Pharma Comm in March and July 2022, respectively, to advance the commercialization of our long-acting COVID-19 neutralization antibody therapy in China.

Next Achievements and Upcoming Readouts

- The U.S. FDA is currently reviewing the Company's Emergency Use Authorization application for the amubarvimab/romlusevimab combination.
- An investigator-initiated Phase 2 randomized, single-blind, placebo-controlled study is planned by the First Affiliated Hospital of Guangzhou Medical University, aiming at evaluating the level of enhanced SARS-CoV-2 specific immunity after single infusion of monoclonal neutralizing antibody therapy, amubarvimab/romlusevimab combination, in immunocompromised population.

Central Nervous System Disease Program (Internally discovered. U.S. team core project):

We are developing BRII-296 and BRII-297 to address the challenges associated with current treatments for PPD/MDD and other anxiety or depressive disorders. We are doing this by leveraging insight gained from, and applying drug formulation know-how utilized in, developing long-acting therapies where drug administration convenience and patient compliance are critical to potential treatment success.

BRII-296: BRII-296 is our novel and single treatment option for the treatment and prevention of PPD. It acts as a gamma-aminobutyric acid A receptor positive allosteric modulator. BRII-296 is currently in clinical Phase 1 study.

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

- We are investigating the use of BRII-296 in patients with severe PPD or those at high risk of developing PPD. As there is currently no approved therapy to prevent PPD, we believe BRII-296 has the potential to shift the paradigm of PPD treatment and prevention.
- Our Phase 1 SAD study for BRII-296 is ongoing.

Next Achievements and Upcoming Readouts

- We expect to complete enrollment in the third quarter of 2022. The initial safety, tolerability and PK data will be shared at a scientific conference in the second half of this year.
- We have requested a Type C meeting with the U.S. FDA to align on our clinical development plan for both PPD treatment and prevention. We aim to start the PPD treatment study before the end of 2022.

BRII-297: BRII-297 is a new chemical entity discovered internally. BRII-297 is under development for treatment of various anxiety and depressive disorders.

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

- We are conducting IND-enabling studies with BRII-297 targeting various anxiety and depression disorders.

Next Achievements and Upcoming Readouts

- We aim to initiate the Phase 1 study for BRII-297 in the fourth quarter of 2022.

HIV Program (Internally discovered. U.S. team core project)

We are developing BRII-778 and BRII-732 as a once-weekly single-tablet combination therapy that will offer a more discreet, convenient and non-invasive maintenance therapy for HIV patients.

BRII-778: 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.

Next Achievements and Upcoming Readouts

- Safety, tolerability and pharmacokinetic data from this study will be presented at Infectious Disease Week Conference in October 2022.

BRII-732: BRII-732 is a new chemical entity that is metabolized upon oral administration into EFdA or islatravir. EFdA functions not only as a potent chain-terminator like other NRTIs, but also as a potent HIV reverse transcriptase translocation inhibitor, with high binding affinity to the active site of reverse transcriptase, that inhibits HIV reverse transcriptase by blocking translocation of nascently synthesized strand(s) for the next nucleotide incorporation.

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

- We completed our Phase 1 SAD/MAD study of BRII-732 in May 2022.
- We have received an initial response from the U.S. FDA outlining the requirements for release of clinical hold and further clarification is ongoing. We are working closely with the U.S. FDA to align on our understanding of the safety signal identified in the islatravir related studies.

Next Achievements and Upcoming Readouts

- We plan to present safety, tolerability and PK data for our Phase 1 SAD/MAD study at Infectious Disease Week Conference in October 2022.
- The long-term toxicology data will be available by the end of 2022 and may provide additional evidence to support resumed clinical work.
- We will continue to actively correspond with the U.S. FDA to discuss our plan to further investigate and develop BRII-732. Our aim is to lift the clinical hold as soon as we can in 2022 and proceed with the development of our once-weekly oral combination of BRII-732 and BRII-778.

MDR/XDR Gram-negative Infections Program (Licensed from Qpex. China team core project)

We are developing our MDR/XDR therapies in collaboration with our partner Qpex as part of its global development plan. We retain responsibility for the development and regulatory activities in the Greater China, while Qpex is responsible for all development and regulatory activities outside the 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 when we are expected to join China as part of the global studies. BRII-636, BRII-672 and BRII-693 candidates all obtained QIDP designation from the U.S. FDA, which may receive incentives in the future. We are collaborating with Qpex to progress OMNIvance® (BRII-636, a broad spectrum BLI, in combination with an IV β -lactam antibiotic) and ORAvance™ (BRII-672, a broad spectrum BLI in combination with an oral β -lactam antibiotic) and BRII-693 (a novel lipopeptide IV antibiotic) for the treatment of bacterial infections for which there are critical needs for new antibiotic treatments.

BRII-636 (BLI of OMNIvance®): BRII-636 is a novel cyclic boronic acid derived broad-spectrum inhibitor designed to cover all major SBLs and MBLs to restore the bacterial activity of multiple carbapenems and cephalosporins. It is administered by IV to deliver BRII-636 into the bloodstream.

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

- In early 2022, our partner, Qpex, announced that BRII-636 (INN: xeruborbactam) received Qualified Infectious Disease Product designation by the U.S. FDA.
- Qpex has completed enrollment in a first-in-human Phase 1 study and a drug-drug interaction study.

Next Achievements and Upcoming Readouts

- The results are expected to be shared by Qpex for its Phase 1 study in the fourth quarter of 2022 at a scientific conference.
- We will submit an IND application to China's NMPA in due course.

BRII-672 (BLI of ORAvance™): BRII-672 is a prodrug of BRII-636 that can be administered orally to deliver BRII-636 into the bloodstream. 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 received QIDP designation by the U.S. FDA, and its Phase 1 study is progressing and on track to be completed.

Next Achievements and Upcoming Readouts

- We will submit an IND application to China's NMPA in due course.

BRII-693 (QPX-9003): BRII-693 is a novel synthetic lipopeptide, which has emerged as a development candidate based on a combination of increased in vitro and in vivo potency, and an improved safety profile as compared to currently available polymyxins. BRII-693 has the potential to represent a significant advancement in the polymyxin class of hospital (IV) 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.
- Enrollment in the first-in-human Phase 1 clinical study has been completed, including a cohort of Chinese subjects.

Next Achievements and Upcoming Readouts

- Qpex expects to share top-line data in the fourth quarter of 2022.
- We will submit an IND application with China's NMPA in due course.

MDR/XDR Mycobacterium Tuberculosis and Nontuberculosis Mycobacteria Program (Licensed from AN2. China team core project)

We are developing epetraborole (BRII-658) in MDR/XDR TB and NTM with AN2. Epetraborole (BRII-658) is a novel antibiotic that has shown potent and broad-spectrum activity against mycobacteria and other bacterial pathogens in a Phase 1b trial. AN2 is conducting a pivotal Phase 2/3 clinical trials of epetraborole (BRII-658) for the treatment of treatment-refractory MAC lung disease. We hold a license to develop, manufacture, and commercialize epetraborole (BRII-658) in Greater China.

BRII-658 (epetraborole): BRII-658 is an antibiotic with a novel mechanism of action. It is a boron-containing, orally available, 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)

- In June 2022, AN2 initiated patient screening for the pivotal Phase 2/3 clinical trial for treatment-refractory MAC lung disease.

Next Achievements and Upcoming Readouts

- AN2 has completed the enrollment for a Phase 1 bridging study in Japan, and topline data are pending.

Other Corporate Developments

- We expanded our diverse global executive team with the additions of Dr. Susannah Cantrell as our Chief Business Officer, Dr. Eleanor (Ellee) de Groot as our Senior Vice President, Chief Technology Officer, Ms. Karen D. Neuendorff as our Chief People Officer and Dr. Aleksandar Skuban as our Vice President, CNS Disease Therapy Area Head. Each of these accomplished industry executives boasts a strong track record of success in leading international teams.
- 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.
- In April 2022, we released our inaugural ESG report along with the 2021 annual report. 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.
- We sponsored 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. These types of events would foster relationships with patients, their caregivers, and the disease-specific nonprofit groups that support them. We believe, it will ensure patients' voices are understood across every function, from R&D to commercialization.

For more information on how we are working to make the world and the Company a better place, please see our 2021 ESG report available on the Company's website.

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 HIV and earlier stage CNS 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, COVID-19 and MDR/XDR. 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 depression 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; President and General Manager of Greater China Mr. Yongqing Luo; Chief Medical Officer Dr. Li Yan; Senior Vice President, Head of Medicinal Chemistry Dr. Lianhong Xu; Senior Vice President, Head of Pharmaceutical Research Dr. Qing Zhu; Senior Vice President, Head of U.S. Market Access and Patient Advocacy Mr. Coy Stout; and Vice President, Head of Infectious Disease Therapy Area Dr. David Margolis.

In the first half of the year, we added four additional leaders to our senior executive team to broaden and deepen the scope of our management. These hires included additions of Dr. Susannah Cantrell as our Chief Business Officer, Dr. Eleanor (Ellee) de Groot as our Senior Vice President, Chief Technology Officer, Ms. Karen D. Neuendorff as our Chief People Officer and Dr. Aleksandar Skuban as our Vice President, CNS Disease Therapy Area Head. Each of these accomplished industry executives boasts a strong track record of success in leading international teams.

Dr. Susannah Cantrell joined our team as Chief Business Officer in July 2022. She brings us more than 20 years of healthcare and biotechnology industry experience spanning global pipeline strategy, sales, operations, marketing and new product commercialization. Her prior positions include senior executive leadership positions at Second Genome, Inc., Tricida, Inc. and Gilead Sciences, Inc.

Dr. Eleanor (Ellee) de Groot joined the Company in August 2022. She has more than two decades of experience of leading a wide range of streamlined global operations across growing biotechnology companies, from early to late stage clinical development and commercial-scale manufacturing.

With more than 25 years' experience in the biopharmaceutical industry, Dr. Zhi Hong previously led the infectious diseases departments of various multinational pharmaceutical companies, including GSK. He is widely credited as the key architect of GSK's comeback with notable success in HIV and other infectious diseases medicine discovery and development.

Mr. Yongqing Luo is responsible for running the Company's business in China while supporting the Company's growth in the U.S. During his tenure at Gilead Sciences, Inc., he led the product launches of several high-profile medicines, and pioneered new patient access solutions through collaborations with commercial insurance companies and government agencies.

Dr. David Margolis has extensive experience in clinical development of infectious disease products. He is responsible for our clinical programs in infectious diseases in the U.S. and provides strategic input and support for the clinical programs in China.

Dr. Aleksandar Skuban joined us to spearhead our CNS program development, bringing his more than 25 years of global pharmaceutical research and development experience. He holds an extensive medical, scientific and business leadership track record of achievements, which include leading more than 30 studies across therapeutic areas from early-stage proof of concept through positive regulatory outcomes, with a focus in CNS diseases.

As a leader in public health and biopharmaceutical industry, Mr. Coy Stout establishes strategic commercial planning and infrastructure to help advancing patient access in the U.S. to important medications across a variety of disease areas, especially infectious diseases.

Dr. Lianhong Xu brings us her vast experience as the co-inventor of several successful antiviral therapies at Gilead Sciences, Inc. where she led the discovery efforts in many therapeutic areas against HIV, Hepatitis C, HBV and cancers resulting in numerous clinical candidates.

Developing and driving the execution of the Company's clinical development programs and registrations, Dr. Li Yan leverages his experience as the former lead of GSK Oncology, where he oversaw global development of oncology assets focusing on immunotherapy, cancer epigenetics, and cell therapy.

Dr. Qing Zhu leads our biopharmaceutical research, with her extensive R&D experience including spearheading the antiviral R&D programs at MedImmune progressing antibody candidates from discovery through the clinic and regulatory submissions.

With widely respected members in the 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 RMB258.5 million for the first six months of 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.

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 highly focused on our core development programs in HBV in China, where we are an industry frontrunner, as well as our depression disorders programs, where we are accelerating our clinical development in depression treatment, particularly PPD in the United States.

Having quickly pivoted in 2020 and 2021 to serve the greater global needs compelled by COVID-19 and its variants, we were able to rapidly move through the clinical, regulatory and commercialization processes to bring our product to market within 27 months. Next, we'll carry forward the experience gained from our COVID-19 program to expand and advance our other public health-inspired clinical programs with the goal of bringing proven and meaningful long-term therapeutic solutions to patients and the healthcare community.

Our strategic priorities for the second half of 2022 are to:

- o Advance BRII-179 (VBI-2601) and BRII-835 (VIR-2218) combination (therapeutic vaccine and siRNA combination therapy designed) and BRII-179 (VBI-2601) with PEG-IFN- α (therapeutic vaccine in HBV patients receiving PEG-IFN- α and NRTI treatment) to provide functional cures for HBV infection in the Greater China;
- o Under the lead of our newly joined CNS Disease Therapy Area Head, continue to advance the clinical development of BRII-296 for the treatment and prevention of postpartum depression, as well as BRII-297 for the treatment of various anxiety and depression disorders;
- o Ensure sufficient supply of amubarvimab/romlusevimab antibodies for commercial use, and extend our product accessibility in other countries;
- 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 United States to support our developing business and establish a global patient-centric/people strategy built on a strong cultural foundation that lives through our mission to tackle the world's biggest challenges in public health.

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 July 2022. Shortly thereafter, TSB Therapeutics entered into a strategic partnership with CR Pharma Comm to advance stockpiling, channel distribution and hospital access for our long-acting neutralizing monoclonal antibody therapy, the amubarvimab/romlusevimab combination. We are working together to ensure timely drug supply that supports the COVID-19 pandemic prevention and control efforts in China. The collaboration will also explore other novel partnership opportunities to enable expanded access of the combination therapy in China.

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, we do not anticipate sales or commercialization of drug candidates outside of our COVID-19 therapy in the immediate future.

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

Subsequent Event

On July 4, 2022, the Company announced that it exercised its option to in-license BRII-877(VIR-3434), a broadly neutralizing monoclonal antibody targeting HBV, for its exclusive development and commercialization rights in Greater China as part of its broader collaboration with Vir.

For details, please refer to the announcement of the Company dated July 4, 2022.

FINANCIAL REVIEW

1. Other income

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Government grants	27,885	45,660
Bank interest income	10,343	620
	<hr/>	<hr/>
Total	<u>38,228</u>	<u>46,280</u>

Our other income decreased by RMB8.1 million from RMB46.3 million for the six months ended June 30, 2021 to RMB38.2 million for the six months ended June 30, 2022. This was primarily due to the decrease in the recognition of government grants income of RMB17.8 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. The decrease in government grants income was partially offset by the increase in bank interest income of RMB9.7 million. The increase in bank interest income was primarily attributable to the increase in bank and cash balances after the Global Offering.

2. Other gains and losses

Our other gains and losses decreased by RMB34.0 million from losses of RMB9,000 for the six months ended June 30, 2021 to losses of RMB34.0 million for the six months ended June 30, 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.

3. Fair value loss on financial liabilities at FVTPL

Our fair value loss on financial liabilities at FVTPL decreased by RMB2,751.6 million from RMB2,751.6 million for the six months ended June 30, 2021 to nil for the six months ended June 30, 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 period. 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.

4. Fair value (loss) gain on equity instrument at FVTOCI

Our fair value (loss) gain on equity instrument at FVTOCI decreased by RMB31.7 million from gain of RMB8.9 million for the six months ended June 30, 2021 to loss of RMB22.8 million for the six months ended June 30, 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.

5. R&D expenses

	Six months ended June 30,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Third-party contracting cost	168,357	99,678
Employee cost	80,223	49,673
Licensing fees	6,487	6,476
Amortization	1,358	1,358
Others	2,059	426
Total	<u>258,484</u>	<u>157,611</u>

Our R&D expenses increased by RMB100.9 million from RMB157.6 million for the six months ended June 30, 2021 to RMB258.5 million for the six months ended June 30, 2022. The increase was primarily attributable to the increase in third party contracting cost of RMB68.7 million, which was mainly due to Good Manufacturing Practice related activities in China for our amubarvimab/romlusevimab combination therapy. In addition, employee cost increased by RMB30.6 million due to the increase in R&D headcounts during the Reporting Period.

6. Administrative expenses

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Employee cost	63,222	44,910
Professional fees	15,751	6,833
Depreciation and amortization	6,956	6,564
Office expenses	2,088	1,368
Others	7,450	8,315
	<hr/>	<hr/>
Total	95,467	67,990
	<hr/> <hr/>	<hr/> <hr/>

Our administrative expenses increased by RMB27.5 million from RMB68.0 million for the six months ended June 30, 2021 to RMB95.5 million for the six months ended June 30, 2022. This was primarily attributable to an increase of RMB18.3 million in employee costs from RMB44.9 million for the six months ended June 30, 2021 to RMB63.2 million for the six months ended June 30, 2022. Such increase was primarily attributable to the increase in employee headcount, as well as the increase in stock compensation expense for employees. In addition, professional fees increased by RMB8.9 million mainly due to the professional services required as a listed company following the Global Offering.

7. Selling and marketing expenses

Our selling and marketing expenses primarily consist of employee related costs and pre-launch activity expenses for amubarvimab/romlusevimab combination therapy. We established a commercial team in order to better support our new product launch and distribution.

8. Liquidity and Capital resources

At June 30, 2022, our bank and cash balances, including restricted bank deposits and time deposits, decreased to RMB3,221.9 million from RMB3,355.1 million at December 31, 2021. The decrease is primarily due to payout of daily operations and third party contracting costs.

9. Non-IFRS measures

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

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

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

	Six months ended June 30,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Loss for the period	(365,614)	(2,953,579)
Added:		
Share-based compensation	53,988	27,391
Fair value loss on financial liabilities at fair value through profit or loss (“FVTPL”)	–	2,751,575
Listing expenses	–	21,781
	<u>–</u>	<u>21,781</u>
Adjusted loss for the period	<u>(311,626)</u>	<u>(152,832)</u>

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

	Six months ended June 30,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
R&D expenses for the period	(258,484)	(157,611)
Added:		
Share-based compensation	22,082	5,252
	<u>22,082</u>	<u>5,252</u>
Adjusted R&D expenses for the period	<u>(236,402)</u>	<u>(152,359)</u>

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

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Administrative expenses for the period	(95,467)	(67,990)
Added:		
Share-based compensation	<u>25,901</u>	<u>22,139</u>
Adjusted administrative expenses for the period	<u>(69,566)</u>	<u>(45,851)</u>

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

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Selling and marketing expenses for the period	(15,376)	–
Added:		
Share-based compensation	<u>6,005</u>	<u>–</u>
Adjusted administrative expenses for the period	<u>(9,371)</u>	<u>–</u>

10. Key financial ratios

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

	At	At
	June 30,	December 31,
	2022	2021
Current ratio ⁽¹⁾	1,068%	1,216%
Gearing ratio ⁽²⁾	NM	NM

(1) Current ratio is calculated using current assets divided by current liabilities as of the same date. Current ratio decreased mainly due to the decrease in cash balances as we pay out for our daily operations and third party contracting costs.

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

11. Indebtedness

Borrowings

At June 30, 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

At June 30, 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. At June 30, 2022, the Group had lease liabilities of RMB17.5 million recognized under IFRS 16.

12. Significant investments, material acquisitions and disposals

At June 30, 2022, we did not hold any significant investments. For the six months ended June 30, 2022, we did not have material acquisitions or disposals of subsidiaries, associates, and joint ventures.

13. Charge on the Group's assets

At June 30, 2022, none of the Group's assets were charged with any parties or financial institutions (December 31, 2021: nil).

14. Foreign exchange exposure

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

As at June 30, 2022, the Group's restricted bank deposits, time deposits with original maturity over three months and bank balances and cash were denominated as to 48.1% in US dollars, 31.5% in Hong Kong dollars, and 20.4% in RMB.

15. Employees and remuneration

As at June 30, 2022, we had a total of 123 employees. The following table sets forth the total number of employees by function at June 30, 2022:

Function	Number of employees	% of total
R&D	73	59%
Administration	39	32%
Selling and marketing	11	9%
Total	<u>123</u>	<u>100%</u>

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

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

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

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

The total remuneration cost incurred by the Group for the six months ended June 30, 2022 was RMB157.4 million, as compared to RMB94.6 million for the six months ended June 30, 2021.

16. 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 NET PROCEEDS FROM LISTING

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. The Company intends to apply such net proceeds in accordance with the purposes as set out in the Prospectus.

The table below sets out the planned applications of the net proceeds from the Global Offering and the partial exercise of the over-allotment option and the actual usage up to June 30, 2022:

Use of proceeds	Percentage of total net proceeds	Allocation of net proceeds (HK\$ million)	Utilized amount as of June 30, 2022 (HK\$ million)	Unutilized amount as of June 30, 2022 (HK\$ million)
Used for our HBV functional cure programs	55%	1,437.6	95.1	1,342.5
– To fund ongoing and planned clinical trials, preparation for registration filings, milestone payments and other steps and activities related to commercialization for BRII-179, our Core Product	50%	1,306.9	80.8	1,226.1
• To fund ongoing and planned clinical trials and preparation for regulatory filings for BRII-179/BRII-835 combination therapy in chronic HBV patients	20%	522.8	41.4	481.4
• To fund planned clinical trials and preparation for regulatory filings for BRII179/PEG-IFN- α combination therapy in chronic HBV patients	16%	418.2	3.8	414.4
• To fund planned clinical trials and preparation for regulatory filings for BRII-179 in combination with other drug candidates with complimentary mechanism of actions	8%	209.1	35.6	173.5
• Used for regulatory milestone payments for BRII-179	1%	26.1	–	26.1
• Used for the launch and commercialization of BRII-179 (as a monotherapy and/or combination therapy)	5%	130.7	–	130.7
– Used to fund additional ongoing and planned clinical trials and the preparation for registration filings for BRII-835	5%	130.7	14.3	116.4
Used for our HIV programs, funding the ongoing and planned clinical trials and preparation for registration filings for BRII-778 and BRII-732	15%	392.1	81.8	310.3
Used for our MDR/XDR gram-negative infections programs	15%	392.1	25.9	366.2
– To fund the ongoing and planned clinical trials and preparation for registration filings for BRII636, BRII-672 and BRII-693	9%	235.2	17.4	217.8
– Used for regulatory milestone payments for BRII636, BRII-672 and BRII-693	6%	156.9	8.5	148.4
To fund the ongoing and planned clinical trials and preparation for registration filings for BRII-296	5%	130.6	54.1	76.5
Used for our early-stage pipeline, business development initiatives, working capital and general corporate purposes	10%	261.4	261.4	–
Total		2,613.8	518.3	2,095.5

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

INTERIM DIVIDEND

The Board does not declare the payment of an interim dividend for the six months ended June 30, 2022.

CORPORATE GOVERNANCE PRACTICES

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

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

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

The balance of power and authority is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises two executive Directors, two non-executive Directors and four 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 (“**Company’s Code**”) on terms no less exacting than the required standard set out in the Model Code as set out in Appendix 10 to the Listing Rules. Having made specific enquiry with the Directors, all Directors confirmed that they have complied with the required standard as set out in the Model Code and the Company’s Code during the Reporting Period. No incident of non-compliance of the Model Code or the Company’s Code by the relevant employees who are likely to be in possession of unpublished inside information of the Company was noted by the Company.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

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

REVIEW OF INTERIM RESULTS

The external auditors of the Company, namely Deloitte Touche Tohmatsu, have carried out a review of the unaudited condensed consolidated financial statements of the Group for the six months ended June 30, 2022 in accordance with the Hong Kong Standard on Review Engagement 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants.

The Board has established the Audit Committee which comprises three independent non-executive Directors, namely Ms. Grace Hui Tang, Dr. Martin J Murphy Jr and Mr. Yiu Wa Alec Tsui. Ms. Grace Hui Tang serves as the chairlady of the Audit Committee, who has the professional qualification and experience in financial matters in compliance with the requirements of the Listing Rules. The primary duties of the Audit Committee are to review and supervise the Company’s financial reporting process and internal controls.

The Audit Committee, together with the management of the Company, has reviewed the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the unaudited condensed consolidated financial statements of the Group for the six months ended June 30, 2022) of the Group, and is of the view that the interim results of the Group is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

PUBLICATION OF THE INTERIM RESULTS ANNOUNCEMENT AND THE INTERIM REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.briibio.com). The interim report of the Company for the six months ended June 30, 2022 containing all the information required by the Listing Rules will be despatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

DEFINITIONS

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

“ACTIV”	Accelerating COVID-19 Therapeutic Interventions and Vaccines program
“ACTIV-2”	The clinical trials of outpatient monoclonal antibodies and other therapies under the Accelerating Covid-19 Therapeutic Interventions and Vaccines program
“AIDS”	Acquired immunodeficiency syndrome, defined as an HIV infection with either a CD4+ T-cell count below 200 cells per μ L or the occurrence of specific diseases associated with HIV infection
“AN2”	AN2 Therapeutics, Inc., a corporation incorporated in Delaware, U.S., whose stocks are listed on the NASDAQ Global Select Market (NASDAQ: ANTX)

“ART”	antiretroviral therapy
“Audit Committee”	the audit committee of the Company
“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(s), a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“CG Code”	the Corporate Governance Code contained in Appendix 14 to the Listing Rules
“China” or “the PRC”	the People’s Republic of China excluding, for the purposes of this announcement, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“CMO”	Contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide drug manufacturing services
“CNS”	central nervous system, part of the nervous system consisting of the brain and spinal cord
“Company”, “we”, or “us”	Brii Biosciences Limited (騰盛博药生物科技有限公司) (formerly known as BiiG Therapeutics Limited and B.I.G. Therapeutics Limited), an exempted company with limited liability incorporated under the laws of the Cayman Islands on December 8, 2017, the Shares of which are listed on the Main Board of the Stock Exchange
“Core Product”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules
“COVID-19”	Coronavirus Disease 2019, a disease caused by the novel virus 2 SARS – CoV-2 and designated as severe acute respiratory syndrome
“CR Pharma Comm”	China Resources Pharmaceutical Commercial Group Co., Ltd.
“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
“GMP”	the Good Manufacturing Practice
“Greater China”	Mainland China, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“Group”	the Company and its subsidiaries
“GSK”	GlaxoSmithKline plc., a company listed on the New York Stock Exchange in the United States (stock code: GSK)
“HBeAg”	hepatitis B e antigen
“HBsAg”	hepatitis B surface antigen
“HBV”	hepatitis B virus
“HIV”	human immunodeficiency virus
“Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic China
“HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“HR”	human resources
“IASB”	International Accounting Standards Board
“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
“MBL(s)”	Metallo-Beta-lactamases, a subclass of lactamases that use one of two Zinc ions in their active site
“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
“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
“NTM”	non-tuberculosis mycobacteria
“PEG-IFN- α ”	pegylated interferon alfa
“PK”	pharmacokinetics
“PPD”	postpartum depression
“Prospectus”	the prospectus of the Company dated June 30, 2021

“QIDP”	Qualified Infectious Disease Product
“Qpex”	Qpex Biopharma Inc., a corporation incorporated in Delaware, United States
“Reporting Period”	the six months ended June 30, 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
“SBL(s)”	Serine-lactamases, a diverse set of enzymes sharing several highly conserved amino acid sequences with penicillin binding proteins that act as a catalyst to break down a broad range of -lactam drugs, including carbapenems
“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)
“Sinopharm Group”	Sinopharm Group Co. Ltd., a joint stock company incorporated in the PRC with limited liability, whose shares are listed on the Stock Exchange with stock code 1099
“siRNA”	Small interfering RNA, sometimes known as short interfering RNA or silencing RNA, a class of double stranded non-coding RNA molecules
“Stock Exchange”	the Stock Exchange of Hong Kong Limited
“TB”	tuberculosis, a contagious infection caused by bacteria
“TSB Therapeutics”	TSB Therapeutics Ltd (Beijing) Co. Limited, a limited liability company incorporated in the PRC, being an indirect non-wholly owned subsidiary of the 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
Brii Biosciences Limited
Dr. Zhi Hong
Chairman

Hong Kong, August 24, 2022

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