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# Jiangsu Recbio Technology Co., Ltd.

江蘇瑞科生物技術股份有限公司

(a joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2179)

# ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022 AND CHANGE IN USE OF PROCEEDS

The Board is pleased to announce the audited condensed consolidated results of the Group for the year ended December 31, 2022, together with the audited comparative figures for the year ended December 31, 2021.

### **BUSINESS HIGHLIGHTS**

In 2022 and as of the date of this announcement, we have made significant progress in many aspects:

# Further promoting the development of innovative vaccines at the clinical-trial stage

### REC603 - HPV Recombinant HPV 9-Valent Vaccine

The 9-valent HPV vaccine provides protection about 90% of cervical cancers and 90% of anal and genital warts, and is widely considered the most effective vaccine against HPV. At present, no domestic 9-valent HPV vaccine has been approved for sale in China.

- We are in the process of conducting phase III clinical trial in China. The phase III clinical trial in China consists of three parts, i.e. the efficacy trial, the immuno-bridging trial in younger-age groups, and the immunogenicity comparative trial with Gardasil®9, with a multicenter, randomized, blinded and parallel controlled design and with a total size of 16,050 subjects. The Company has completed the most of the three-dose vaccination of the two studies of REC603 immuno-bridging trial in younger-age groups and the immunogenicity comparative trial with Gardasil®9. At the same time, follow-up on the subjects of REC603's efficacy trial is being conducted in accordance with the clinical protocol. We plan to submit BLA application to the NMPA for REC603 in 2025.
- Efficacy trial: To evaluate the protective efficacy of the vaccines in healthy female subjects aged 18 to 45 against high-risk HPV infection-related high-grade cervical, vulvar, vaginal high-grade intraepithelial neoplasia and above lesions.
- Immuno-bridging trial in younger-age groups: To evaluate the non-inferiority of serum virus neutralizing antibodies in healthy female subjects aged 9 to 17 as compared with healthy female subjects aged 18 to 45 at one month after full-course vaccination with the experimental vaccines.

- Immunogenicity comparative trial with Gardasil®9: To evaluate the non-inferiority of serum virus neutralizing antibodies in healthy female subjects aged 16 to 26 as compared with Gardasil® 9 at one month after full-course vaccination with the experimental vaccines.
- In order to meet the rapidly growing market demand for HPV 9-valent vaccine in domestic and the international market, after process optimization, facility upgrading and verification, the peak production capacity for the first phase of the HPV vaccine manufacturing facility of the Company will be increased to an annual output of 20 million doses of HPV 9-valent vaccine.

# REC610 - Novel Adjuvanted Recombinant Shingles Vaccine

Shingles is an acute infectious skin disease caused by reactivation of latent varicella zoster virus (VZV) in the body. There is no specific medicine for shingles, and vaccine is an effective means of preventing shingles. According to research data on shingles vaccines that have been marketed around the world, the novel adjuvanted vaccine can provide stronger cellular immunity and protective efficacy as compared to live attenuated vaccines.

- On December 19, 2022, the Company received clinical trial approval from the Philippine National Food and Drug Administration. And the Company completed the first batch of subject enrollment on February 13, 2023. The study is a randomized, observer-blinded, GSK Shingrix® active-controlled phase I clinical trial to evaluate the safety and immunogenicity of REC610 in healthy adult subjects aged 40 and above.
- REC610 is equipped with a novel adjuvant BFA01 independently developed by the Company, which can promote the production of high levels of VZV glycoprotein E (gE)-specific CD4+T cells and antibody. Preclinical studies have shown that REC610 has favorable immunogenicity and can induce high levels of gE-specific CD4+ T cell responses and IgG antibody, and its immune response is non-inferior to the controlled vaccine Shingrix®.

# ReCOV - Recombinant Two-Component COVID-19 Vaccine

ReCOV is a recombinant COVID-19 vaccine being developed by the Company with its technology platforms including the novel adjuvant, protein engineering and immunological evaluation platforms, and the adjuvant used therein is the self-developed novel adjuvant BFA03. It has a variety of comprehensive advantages, including favorable neutralizing effect and immune persistence, overall positive safety profile, potential growth in production scale, low production cost, preparation stability, and ability to be stored and transported at room temperature.

- In December 2022, positive results were achieved for its sequential booster vaccination Phase II study in the Philippines. This clinical study aims to compare the immunogenicity and safety profile of ReCOV and Pfizer's mRNA vaccine, COMIRNATY® as booster vaccination among subjects who have completed primary vaccination of inactivated vaccines. The results showed that the overall safety was outstanding with mild adverse reactions and no vaccine-related serious adverse events. The levels of neutralizing antibodies against the prototype and Omicron variant strains (B.7, BA.5, BA.2.75 and BA.2) induced by ReCOV sequential booster were superior than those of Pfizer's mRNA vaccine (with significant differences statistically).
- In December 2022, the first batch of subject enrollment in the ReCOV international multicenter Phase III clinical trial was completed.

• The vaccine manufacturing facility for ReCOV in Taizhou received the European Union (EU) Qualified Person Declaration issued by a Qualified Person ("QP").

# REC604a - Novel Adjuvanted Recombinant HPV 4-valent vaccine

REC604a is equipped with BFA04, a novel adjuvant developed by the Company, which is designed to reduce the number of doses by enhancing immunogenicity and cross-protection. Fewer doses are recommended by regulators such as the WHO so as to save costs and increase vaccination rates.

- The Company has received implied license for conducting clinical trials in China.
- Preclinical studies showed that BFA04 adjuvant increased neutralizing antibodies by 7.7 times compared with aluminum adjuvant. Compared with three doses of Gardasil®, the levels of HPV neutralizing antibodies induced by two doses of REC604a were higher than those induced by three doses of Gardasil®. Until 24 weeks after the last immunization, the decrease trend of neutralizing antibody titers produced by REC604a immunization was more gentle than that of Gardasil®.

# REC601 - Recombinat Bivalent(16/18) Vaccine

- REC601 adopted a similar expression system and process route to REC603, a recombinant HPV 9-valent vaccine.
- Data evaluation and analysis of Phase I clinical trials in China have been completed. Data from Phase I trial showed that REC601 demonstrated favorable safety and immunogenicity in healthy women subjects aged 9-45 years. There were no grade 4 or higher adverse events or serious adverse events associated with the experimental vaccine. 30 days after the full immunization: the antibody positive rates of HPV16 and HPV18 both reached 100.00%, and serum conversion rates of HPV16 and HPV18 were also reached 100.00% in the negative population before immunization. The levels of HPV16 and HPV18 antibodies were also significantly improved: GMT for HPV16 antibody increased 632.99 times and GMT for HPV18 antibody increased 1,194.02 times compared with that before immunization.

# REC602 - Recombinat Bivalent(6/11) Vaccine Targeting HPV

- REC602 adopted a similar expression system and process route to REC603, a recombinant HPV 9-valent vaccine.
- The Phase I clinical trial in China has been completed by the end of 2022.

# R520A - mRNA COVID-19 Vaccine Targeting Omicron Variants

- Clinical trials have been approved in New Zealand, the Philippines, and Hong Kong, China.
- A paper with the title of "Lyophilized mRNA-lipid nanoparticle vaccines with long-term stability and high antigenicity against SARS-CoV-2" on the international academic journal Cell Discovery (IF: 38) was published to report the freeze-dried lipid nanoparticle vaccine against different variants of SARS-CoV-2.

# Continuing to promote preclinical R&D of innovative vaccines

# REC604b - Novel Adjuvanted Recombinant HPV 9-valent Vaccine

Unlike the traditional alum adjuvant that we are currently using, we are conducting early-stage development of next-generation HPV 9-valent formulated with a novel self-developed adjuvant. We plan to submit the IND application to the NMPA in 2023.

# REC606 - Recombinant Adult TB Vaccine

We are conducting early-stage study with respect to a recombinant adult TB vaccine, namely REC606. Our self-developed REC606 utilized both of the protein engineering platform and novel adjuvant technology platform, both of which have the potential to result in better safety profile and immune response.

## REC607 - Virus Vectored Adult TB Vaccine

We have entered into a technology transfer agreement with Shanghai Public Health Clinical Center, pursuant to which, among others, we obtained the know-how and patents with the exclusive global development rights of REC607, a virus vectored adult TB vaccine candidate. This program was recognized as a Major National Science and Technology Project (國家科技重大專項課題) in 2018. We are currently conducting preclinical R&D for our adult vector vaccine.

# REC617 - Recombinant Influenza Quadrivalent Vaccine

We are developing REC617, an early-stage recombinant influenza quadrivalent vaccine and are developing novel adjuvants enhancing tolerability, immunogenicity, length of protection and cross-protection capability.

# REC605 - HFMD Quadrivalent Vaccine

We are leveraging our protein engineering technology to develop a multi-valent hand-foot-and-mouth vaccine, REC605, with increased serotype coverage of EV71, CA16, CA10 and CA6 and enhanced protection.

We cannot guarantee that we will ultimately develop or market our Core Product or other pipeline products successfully. Shareholders and potential investors of our Company are advised to exercise due care when dealing in the Shares of our Company.

# FINANCIAL HIGHLIGHTS

# CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	For	For the year ended December 31,					
	2022	2021	2020	2019			
	RMB'000	RMB'000	RMB'000	RMB'000			
Other income and gains	147,993	27,810	9,551	12,932			
Loss before tax	(735,996)	(657,566)	(179,400)	(138,270)			
Loss for the year	(735,996)	(657,566)	(179,400)	(138,270)			
Loss attributable to owners of							
the parent	(722,703)	(657,561)	(179,400)	(138,270)			
Loss per share – Basic and diluted							
(in RMB)	(1.52)	(1.56)	(0.58)	(0.48)			

# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As at December 31,				
	2022	2021	2020	2019	
	RMB' 000	RMB '000	RMB'000	RMB '000	
Total non-current assets	889,687	624,649	337,638	115,895	
Total current assets	1,419,920	1,294,571	709,376	310,650	
Total current liabilities	328,983	139,293	57,481	17,798	
Net current assets	1,090,937	1,155,278	651,895	292,852	
Total assets less current liabilities	1,980,624	1,779,927	989,533	408,747	
Total non-current liabilities	327,546	106,631	1,998,317	728,294	
Total (deficit)/equity	1,653,078	1,673,296	(1,008,784)	(319,547)	
Total current assets Total current liabilities Net current assets Total assets less current liabilities Total non-current liabilities	1,419,920 328,983 1,090,937 1,980,624 327,546	1,294,571 139,293 1,155,278 1,779,927 106,631	709,376 57,481 651,895 989,533 1,998,317	310,65 17,79 292,85 408,74 728,29	

# FINANCIAL STATEMENTS AND PRINCIPAL NOTES

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	Notes	2022 RMB'000	2021 RMB'000
Other income and gains	5	147,993	27,810
Selling and distribution expenses		(8,654)	(3,461)
Administrative expenses		(155,302)	(143,045)
Research and development expenses		(716,444)	(472,953)
Other expenses	5	(55)	(9,609)
Finance costs	7 _	(3,534)	(56,308)
LOSS BEFORE TAX	6	(735,996)	(657,566)
Income tax expense	8		
LOSS FOR THE YEAR	<u>-</u>	(735,996)	(657,566)
TOTAL COMPREHENSIVE LOSS			
FOR THE YEAR	=	(735,996)	(657,566)
Attributable to:			
Owners of the parent		(722,703)	(657,561)
Non-controlling interests	_	(13,293)	(5)
	-	(735,996)	(657,566)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	9	(1.52)	(1.56)

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	As at December 31, 2022 RMB'000	As at December 31, 2021 RMB'000
NON-CURRENT ASSETS Property, plant and equipment Other intangible assets Right-of-use assets Goodwill	11	558,710 33,505 72,542 9,305	416,334 22,120 55,274 9,305
Other non-current assets	13	215,625	121,616
Total non-current assets		889,687	624,649
CURRENT ASSETS Inventories Prepayments, other receivables and other assets Cash and bank balances	12	56,160 38,610 1,325,150	23,549 88,460 1,182,562
Total current assets		1,419,920	1,294,571
CURRENT LIABILITIES Trade payables Lease liabilities Interest-bearing bank borrowings Other payables and accruals	10	62,517 20,361 1,394 244,711	16,816 7,862 — 114,615
Total current liabilities		328,983	139,293
NET CURRENT ASSETS		1,090,937	1,155,278
TOTAL ASSETS LESS CURRENT LIABILITIES		1,980,624	1,779,927
NON-CURRENT LIABILITIES Interest-bearing bank borrowings Lease liabilities Deferred income Deferred tax liabilities		231,621 29,251 61,144 5,530	50,000 18,857 32,244 5,530
Total non-current liabilities		327,546	106,631
Net assets		1,653,078	1,673,296
EQUITY Equity attributable to owners of the parent Share Capital Reserves		482,963 1,178,913	448,250 1,225,051
Non-controlling interests		(8,798)	(5)
Total equity		1,653,078	1,673,296

#### 1. CORPORATE AND GROUP INFORMATION

Jiangsu Recbio Technology Co., Ltd. is a joint stock company with limited liability incorporated in the People's Republic of China ("PRC"). The registered office of the Company is located at No. 888 Yaocheng Avenue, Medical High-tech District, Taizhou City, Jiangsu Province, PRC.

During the year, the Company and its subsidiaries (collectively referred to as the "Group") are principally engaged in the research and development of vaccines in the Mainland China.

The Company was listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "Stock Exchange") on March 31, 2022.

### 2. BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs"), which include all standards and interpretations approved by the International Accounting Standards Board ("IASB"). They have been prepared under the historical cost convention. These financial statements are presented in RMB and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

### 3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the financial statements.

Amendments to IFRS 16 Lease Liability in a Sale and Leaseback<sup>2</sup> IFRS 17 Insurance Contracts<sup>1</sup> Amendments to IFRS 17 Insurance Contracts<sup>1,4</sup> Amendment to IFRS 17 Initial Application of IFRS 17 and IFRS 9 – Comparative information<sup>5</sup> Amendments to IAS 1 Classification of Liabilities as Current or Non-current (the "2020 Amendments")<sup>2,3</sup> Non-current Liabilities with Covenants (the "2022 Amendments")<sup>2</sup> Amendments to IAS 1 Disclosure of Accounting Policies<sup>1</sup> Amendments to IAS 1 and IFRS Practice Statement 2 Amendments to IAS 8 Definition of Accounting Estimates<sup>1</sup> Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction<sup>1</sup>

- Effective for annual periods beginning on or after January 1, 2023
- Effective for annual periods beginning on or after January 1, 2024
- As a consequence of the 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after 1 January 1, 2024.
- As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023.
- An entity that chooses to apply the transition option relating to the classification overlay set out in this amendment shall apply it on initial application of IFRS 17.

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group considers that these new and revised IFRSs may result in changes in accounting policies and are unlikely to have a significant impact on the Group's results of operations and financial position.

### 4. OPERATING SEGMENT INFORMATION

For the purpose of resource allocation and performance assessment, the Group's chief executive officer, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment and no further analysis of this single segment is presented.

The Group did not record any revenue during the year and the Group's non-current assets are substantially located in the PRC, accordingly, no analysis of geographical segment is presented.

### 5. OTHER INCOME AND GAINS, AND OTHER EXPENSES

An analysis of other income and gains is as follows:

	Year ended December 31,			
	2022	2021		
	RMB'000	RMB'000		
Other income				
Government grants related to income (i)	5,325	6,199		
Bank interest income	23,975	10,355		
Others	74	40		
Other gains				
Gain on fair value changes of financial assets	3,558	11,216		
Foreign exchange gains, net	115,061			
Other income and gains	147,993	27,810		

<sup>(</sup>i) The government grants and subsidies related to income have been received to compensate for the Group's research and development expenditures and business operations.

An analysis of other expenses is as follows:

	Year ended December 31,		
	2022	2021	
	RMB'000	RMB'000	
Loss on disposal of items of property, plant and equipment	55	19	
Foreign exchange losses, net	_	8,490	
Others		1,100	
	55	9,609	

### 6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

		ecember 31,		
	2022		2021	
No	otes	RMB'000	RMB'000	
Depreciation of property, plant and equipment*	11	27,075	14,903	
Depreciation of right-of-use assets*		13,476	7,555	
Amortisation of intangible assets*		384	_	
Amortisation of other non-current assets*		333	_	
Amortisation of other current assets*		3,067	_	
Interest on lease liabilities		1,914	1,277	
Expense relating to short-term leases*		1,688	490	
Research and development costs		716,444	472,953	
Loss on disposal of items of property, plant and equipment	5	55	19	
Gain on fair value changes of financial assets	5	(3,558)	(11,216)	
Government grants related to income	5	(5,325)	(6,199)	
Foreign exchange differences, net	5	(115,061)	8,490	
Bank interest income	5	(23,975)	(10,355)	
Auditor's remuneration*		2,719	451	
Listing expense		9,932	21,936	
Employee benefit expense* (excluding directors', chief executive's and supervisors' remuneration):				
Wages and salaries		109,199	100,522	
Share-based payments expense		30,325	47,545	
Pension scheme contributions, social welfare and other welfare		10,557	8,716	
Interest charge for redemption liabilities			55,031	

<sup>\*</sup> The depreciation of property, plant and equipment, depreciation of right-of-use assets, amortisation of intangible assets, amortization of other non-current assets, amortization of other current assets, expense relating to short-term leases, auditor's remuneration, listing expense and employee benefit expense for the year are set out in "Selling and distribution expenses", "Administrative expenses" and "Research and development costs" in the interim condensed consolidated statements of profit or loss and other comprehensive income.

## 7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended December 31,		
	2022		
	RMB'000	RMB'000	
Interest on bank borrowings	5,567	1,604	
Less: Interest capitalised	3,947	1,604	
Interest on redemption liabilities on owners' capital	_	55,031	
Interest on lease liabilities	1,914	1,277	
	3,534	56,308	

#### 8. INCOME TAX

The Group's principal applicable taxes and tax rates are as follows:

- (a) No provision for Mainland China income tax has been provided for at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), as the Group's PRC entities have no estimated assessable profits during the year.
- (b) Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), the Company is subject to CIT at a rate of 25% on the taxable income. Beijing ABZYMO obtained its certificate of high-technology enterprise on December 30, 2022 and is entitled to enjoy a preferential tax rate of 15% for three years from 2022 to 2024.
- (c) A reconciliation of the tax expense applicable to loss before tax at the statutory rate to the tax expense at the effective tax rate is as follows:

	Year ended December 31, 2022 RMB'000	Year ended December 31, 2021 RMB'000
Loss before tax	(735,996)	(657,566)
Tax at the statutory tax rate (25%) Lower tax rates for specific provinces or enacted by local authority Expenses not deductible for tax Additional deductible allowance for qualified research and development costs Tax losses and deductible temporary differences not recognized  Tax charge at the Group's effective rate	(183,999) 11,968 12,754 (127,394) 286,671	(164,392) 8,691 48,872 (69,844) 176,673
Deferred tax assets have not been recognised in respect of the following items:		
	As at December 31, 2022 RMB'000	As at December 31, 2021 RMB'000
Tax losses Deductible temporary differences	491,413 55,714	234,859 27,155
	547,127	262,014

The Group has tax losses arising of RMB2,163,611,000 and RMB1,063,757,000, as at December 31, 2022 and 2021.

Deferred tax assets have not been recognised in respect of tax losses and temporary differences as they are not considered probable that taxable profits will be available against which the tax losses can be utilised.

# 9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The Company had no potentially dilutive ordinary shares in issue during the each of the years presented.

The calculation of basic and diluted loss per share is based on:

	Year ended December 31, 2022	Year ended December 31, 2021
Loss Loss attributable to ordinary owners/ordinary equity holders of the parent, used in the basic and diluted loss per share calculation (RMB'000)	(722,703)	(657,561)
Shares Weighted average number of ordinary shares assumed to be in issue during the year used in the basic and diluted loss per share calculation	474,213,311	421,443,519
Loss per share (basic and diluted) (RMB per share)	(1.52)	(1.56)

# 10. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of each reporting period, based on the invoice date, is as follows:

As a December 31	As at December 31,
2022	
RMB'000	RMB'000
Within 1 year       62,507         Over 1 year       10	
62,517	16,816

# 11. PROPERTY, PLANT AND EQUIPMENT

	Leasehold improvements <i>RMB'000</i>	Plant and machinery RMB'000	Furniture and fixtures RMB'000	Computer and office equipment <i>RMB'000</i>	Motor vehicles RMB'000	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
For the year ended 2022							
At January 1, 2022: Cost Accumulated depreciation and impairment	29,207 (6,626)	138,859 (15,762)	176 (62)	3,361 (1,162)	2,179 (571)	266,735	440,517 (24,183)
Net carrying amount	22,581	123,097	114	2,199	1,608	266,735	416,334
At January 1, 2022, net of accumulated depreciation and impairment Additions Disposals Depreciation provided during the year Transfers	22,581 - (6,716) 852	123,097 30,104 (55) (18,581) 21,337	114 24 - (32)	2,199 813 - (1,137) 876	1,608 134 - (609) 370	266,735 150,200 - (35,204)	416,334 181,275 (55) (27,075) (11,769)
At December 31, 2022, net of accumulated depreciation and impairment	16,717	155,902	106	2,751	1,503	381,731	558,710
At December 31, 2022 Cost Accumulated depreciation and impairment	30,059 (13,342)	190,064 (34,162)	200 (94)	5,050 (2,299)	2,683 (1,180)	381,731	609,787 (51,077)
Net carrying amount	16,717	155,902	106	2,751	1,503	381,731	558,710

	Leasehold improvements <i>RMB'000</i>	Plant and machinery <i>RMB'000</i>	Furniture and fixtures <i>RMB'000</i>	Computer and office equipment <i>RMB'000</i>	Motor vehicles RMB'000	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
For the year ended 2021							
At January 1, 2021: Cost Accumulated depreciation and impairment	15,635 (1,117)	62,223 (7,505)	55 (28)	1,194 (532)	1,266 (176)	57,485	137,858 (9,358)
Net carrying amount	14,518	54,718	27	662	1,090	57,485	128,500
At January 1, 2021, net of accumulated depreciation and impairment Additions Disposals Depreciation provided during the year Transfers	14,518 322 - (5,509) 13,250	54,718 58,301 (17) (8,328) 18,423	27 121 - (34)	662 2,176 (1) (638)	1,090 912 - (394)	57,485 240,923 - (31,673)	128,500 302,755 (18) (14,903)
At December 31, 2021, net of accumulated depreciation and impairment	22,581	123,097	114	2,199	1,608	266,735	416,334
At December 31, 2021 Cost Accumulated depreciation and impairment	29,207 (6,626)	138,859 (15,762)	176 (62)	3,361 (1,162)	2,179 (571)	266,735	440,517 (24,183)
Net carrying amount	22,581	123,097	114	2,199	1,608	266,735	416,334

# 12. CASH AND BANK BALANCES

	As at December 31, 2022 RMB'000	As at December 31, 2021 RMB'000
Cash at banks Time deposits	1,169,092 156,058	1,172,562 10,000
Cash and bank balances	1,325,150	1,182,562
Denominated in: RMB USD HKD	205,393 701,487 418,270	494,104 688,458 –

### 13. OTHER NON-CURRENT ASSETS

	As at December 31, 2022 RMB'000	As at December 31, 2021 RMB'000
Time deposits* Prepayment for purchase of property, plant and equipment Prepayment for long-term insurance**	31,404 182,585 1,636	80,000 39,764 1,852
	215,625	121,616

\* As at December 31, 2021, time deposits include (i) RMB50,000,000 starting from December 28, 2020 with a maturity date on December 28, 2023 with a fixed interest rate of 4.10%; (ii) RMB10,000,000 which started from February 23, 2021 with a maturity date on February 23, 2024 with a fixed interest rate of 3.99%; (iii) RMB10,000,000 which started from April 20, 2021 with a maturity date on March 31, 2024 with a fixed interest rate of 3.99%; (iv) RMB10,000,000 which started from June 2, 2021 with a maturity date on February 2, 2024 with a fixed interest rate of 3.41%.

As at December 31, 2022, time deposits include (i) RMB10,000,000 which started from February 23, 2021 with a maturity date on February 23, 2024 with a fixed interest rate of 3.99%; (ii) RMB10,000,000 which started from April 20, 2021 with a maturity date on March 31, 2024 with a fixed interest rate of 3.99%; (iii) RMB10,000,000 which started from June 2, 2021 with a maturity date on February 2, 2024 with a fixed interest rate of 3.41%.

For all the time deposits as at December 31, 2022, interest income is then settled using current interest rate only if to withdraw before corresponding maturity date.

\*\* This is the prepayment of long-term insurance, which will expire in September 2027.

#### 14. DIVIDEND

No dividends have been paid or declared by the Company during the year (2021: Nil).

### MANAGEMENT DISCUSSION AND ANALYSIS

### **BUSINESS REVIEW**

#### Overview

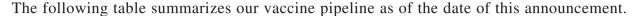
Founded in 2012, we are a vaccine company dedicated to the research, development and commercialization of innovative vaccines, with a high-value innovative vaccine portfolio driven by in-house developed technologies. We primarily focus on the R&D of HPV vaccine candidates. Our vaccine portfolio currently consists of 12 vaccines, including our three strategic products, namely REC603, a recombinant HPV 9-valent vaccine under phase III clinical trial; ReCOV, a recombinant two-component COVID-19 vaccine under marketing application stage; and REC610, a novel adjuvanted recombinant shingles vaccine under clinical research stage.

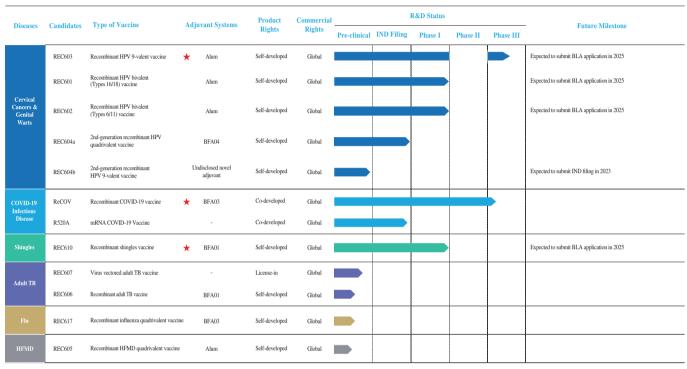
Through years of dedication and focus on this area, we have developed a comprehensive vaccine innovation engine consisting of a novel adjuvant platform, protein engineering platform and immunological evaluation platform. These platforms empower us to continue to discover and develop innovative vaccines that apply advanced technologies in our vaccine candidates. We are one of the few companies that are capable of developing novel adjuvants, benchmarking all of the FDA-approved novel adjuvants to date. Our technology platforms form a "solid trifecta", creating synergies among the design and optimization of antigens, the development and production of adjuvants and the identification of the optimal combinations of antigens and adjuvants. We have also established an IPD System, enabling us to advance the R&D of multiple vaccine candidates simultaneously. Guided by our "OPTI" vaccine development philosophy, we have established a vaccine portfolio consisting of 12 candidates, strategically extending to five of the ten diseases with the greatest burden under the 2019 Global Burden of Diseases assessed by DALYs issued by the WHO and covering disease areas of three of the top five globally bestselling vaccine products in 2020.

We have started to build our manufacturing capabilities at an early stage, aiming at ensuring our vaccine candidates to be smoothly transferred into successful commercial vaccine products. We are constructing our HPV vaccine manufacturing facility in Taizhou, Jiangsu province, the first phase of which has a designed capacity of 20 million doses of HPV 9-valent vaccines per year. In addition, we have completed the construction of our GMP-standard manufacturing facility for ReCOV, a recombinant COVID-19 vaccine, in November 2021, and successfully acquired the production license issued by Jiangsu Medical Products Administration. In April 2022, this manufacturing facility received the European Union (EU) Qualified Person Declaration issued by a Qualified Person (QP), which indicated that the Company's manufacturing facility in Taizhou and its quality management system met the EU GMP standard. This manufacturing facility has a total GFA of approximately 17,000 sq.m., and can also be used for the manufacturing of novel adjuvanted recombinant shingles vaccines.

# **Our Vaccine Pipeline**

Our vaccine portfolio strategically covered six disease areas with significant burden globally, including HPV, COVID-19 infectious disease, shingles, adult TB, flu and HFMD. As of the date of this announcement, our vaccine portfolio consisted of 12 vaccine candidates including, in particular, REC603, a recombinant HPV 9-valent vaccine candidate under phase III clinical trial in China; ReCOV, a recombinant two-component COVID-19 vaccine under marketing application stage; and a novel adjuvanted recombinant shingles vaccine under clinical research stage.





★ Core Product

#### Note:

- 1. Our Core Product REC603, a HPV 9-valent vaccine, obtained the umbrella IND approval from the NMPA in July 2018. The umbrella IND approval covers all three phases (phase I, II and III) clinical trials of REC603. Based on communications with the CDE of the NMPA, the NMPA has no objection for us to proceed with phase III clinical trial in China directly. Accordingly, we did not conduct any phase II clinical trial for REC603.
- 2. Our core product ReCOV, a COVID-19 vaccine, is currently undergoing international multicenter Phase III trials in Russia and Nepal, and is simultaneously undergoing Phase I/II trials for human immune-bridging and sequential booster immunization, as well as investigator-initiated clinical trial (IIT) in China. Currently, the Company is submitting product marketing application to the PRC regulatory authorities on a rolling basis; ReCOV was designed and developed by the Group jointly with Professor Wang Xiangxi's group at the Institute of Biophysics, Chinese Academy of Science.
- 3. REC607 was licensed in from Shanghai Public Health Clinical Center, ID Pharma Co., Ltd. and Shanghai Saimo Biotechnology Ltd.
- 4. All adjuvant systems used in the products under development are self-developed by the Company.
- 5. R520A is an mRNA COVID-19 vaccine candidate developed by Wuhan Recogen, a joint venture established by us and our business partners for the R&D and commercialization of mRNA vaccines. As of the date of this announcement, the Company owned 55% of the equity interest in Wuhan Recogen, which owns all of the future interests of the Company and Shenzhen Rhegen in relation to all infectious disease vaccine products.

# **HPV Vaccine Pipeline**

HPV is the most common viral pathogen of the reproductive tract. Although HPV infections may clear up within a few months without any intervention, certain types of HPVs can persist and develop into cervical cancer. These high-risk HPV infections are mainly caused by HPV types 16, 18, 31, 33, 45, 52 and 58, which account for approximately 90% of cervical cancer cases globally. It is widely accepted that HPV vaccine can play an important role in eliminating cervical cancer as it can prevent HPV infection on certain high risk types. In addition, some cancers of the anus, vulva, vagina, and oropharynx and most genital warts can be prevented by HPV vaccines.

# REC603 - Phase III Stage HPV 9-Valent Vaccine - Our Core Product

REC603, our Core Product, is designed to provide protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. It is expected that REC603 will be one of the first of domestic vaccines of its kind to be approved and commercialized in China.

**Summary of Clinical Trial:** We jointly applied, and obtained the umbrella IND approval for REC603 in July 2018. The umbrella IND approval covers all three phases (phase I, II and III) of clinical trials. In March 2019, we commenced the phase I clinical trial of REC603 in China. We completed phase I clinical trial of REC603 in China in July 2020. Based on communications with the CDE of the NMPA, the NMPA has no objection for us to proceed with phase III clinical trial in China directly. Accordingly, we did not conduct any phase II clinical trial for REC603.

We are in the process of conducting phase III clinical trial in China. The phase III clinical trial in China consists of three parts, i.e., the primary efficacy trial, the immuno-bridging trial in youngerage groups, and the immunogenicity comparative trial with Gardasil®9, with a multi-center, randomized, blinded and parallel controlled design and with a total size of 16,050 subjects. The Company has substantially completed the three doses vaccination of the two studies of REC603 immuno-bridging trial in younger-age groups and the immunogenicity comparative trial with Gardasil®9 as of the date of this announcement. At the same time, follow-up on the subjects of REC603's primary efficacy trial is being conducted in accordance with the clinical protocol. We plan to submit BLA application to the NMPA for REC603 in 2025. Since obtaining the IND approval in China, no material unexpected or adverse changes in relation to REC603 have occurred.

# **Advantages of REC603:** We believe our REC603 has various advantages, including:

Positive immunogenicity profile. REC603 demonstrates a positive immunogenicity profile in its phase I clinical trial. In general, we observed a significant increase in terms of NAb GMT level against all of the target HPV types.

High-yield and stable production of HPV VLPs. REC603 adopts H. polymorpha expression system. In general, the VLPs from different expression systems are all highly similar to natural HPV capsid in structure and epitope in order to trigger immune response after vaccination, including those being produced by H. polymorpha expression system. H. polymorpha, a methylotrophic yeast species, is able to grow to very high cell density rapidly on simple media and has relatively high optimum growth temperature. Owing to its strong and tunable promoters derived from the methanol utilization pathway, high secretion capacity, and lower glycosylation activity compared to S. cerevisiae, H. polymorpha is suitable for production of recombinant proteins for medical use. With high copies of expression cassettes integrated stably in the genome of H. polymorpha, high-yield and stable expression of HPV VLPs is achieved, making our vaccine candidate more suitable for commercial production.

Favorable safety profile. REC603 was safe and well-tolerated as shown in the phase I clinical trial for REC603. There were no statistical differences in terms of incidences of AEs between the vaccine group and the placebo group. Although there is currently no available paper reporting a head-to-head clinical trial comparing domestic HPV vaccines and foreign HPV vaccines, in the clinical trial conducted by Merck Sharp & Dohme for Gardasil 9 in 2009, the rate of adverse event was 86.6% among subjects enrolled in the vaccine cohort, as compared to 53.75% as observed in the phase I clinical trial of REC603. The main adverse reactions were expected fever and inject site pain, mostly were transient and mild.

Scalable manufacturing potential. Our patented technology in HPV VLPs in combination with optimized fermentation strategy and purification process enables us to achieve high and stable yield in bulk production. With well-defined critical process parameters, manufacturing of REC603 can be easily scaled-up to meet the market demand domestically and globally.

*Opportunities and potentials:* We believe there are significant opportunities for our HPV vaccine candidates, considering the following factors:

Superiority of HPV 9-valent vaccines. In general, HPV 9-valent vaccines can provide protection against 90% of cervical cancer and 90% of the anal and genital warts and therefore are the most recommended vaccines for HPV protection. However, to the best knowledge and information of the Company with reference to independent market research, currently there is only one HPV 9-valent vaccine approved in China, and it is expected HPV 9-valent vaccines will account for a larger market share in China after more HPV 9-valent vaccines are approved in China.

Significantly underserved HPV 9-valent vaccine market in China. To the best knowledge and information of the Company with reference to independent market research, even taking into account of the expected growth in vaccination rate of HPV vaccines, there will be 233.9 million females aged 9 to 45 unvaccinated for HPV in 2025, representing a potentially total of 701.7 million doses needed. In addition, the types of HPV serotypes that can infect women can also infect men. Studies have also shown that, males also have similar rates of HPV infection as females. As such, we believe China's HPV vaccine market is, and will continue to be significantly underserved.

The above information was derived from multiple clinical trials conducted for different vaccines without the support of controlled, head-to-head clinical studies, and a number of factors (including the different subject enrollment standards adopted in different trials, different population characteristics of subjects, physicians' inoculation skills and experiences, and lifestyle of the subjects) could affect the relevant clinical results and could render cross-trial comparison results less meaningful.

Domestic substitute. To the best knowledge and information of the Company with reference to independent market research, the first domestic HPV bivalent vaccine accounted for 66.7% of China's HPV bivalent vaccine market in terms of production value in the first year of its launch by virtue of its cost effectiveness, even if it was only approved in 2019 whereas the first imported HPV bivalent vaccine was approved in China in 2016. We believe that considering domestic vaccine products tend to adopt more favorable prices as compared to their global peers, HPV 9-valent vaccines will follow a similar trend in China after being approved. In recent years, the Chinese government has also promulgated policies in favor of domestic HPV vaccine developers. For example, in 2019, the National Health Commission of the People's Republic of China released the Healthy China Action – Cancer Prevention and Control Implementation Plan (2019-2022), stating to accelerate the review and approval process of domestic HPV vaccines and improve the accessibility of HPV vaccines. As one of the few domestic vaccine companies to have phase III stage HPV 9-valent vaccine candidate, we believe we will benefit from such favorable government policies in the future.

Same age coverage as imported vaccines. On August 30, 2022, HPV 9-valent vaccine available in the market in China has been expanded for females aged 9 to 45. Our Core Product, REC603, has also initiated phase III clinical trial for females aged 9 to 45 in 2021, indicating a potential broader coverage in terms of age as compared to the current approved vaccines.

Next-generation HPV vaccines under development. We are also developing next generation HPV quadrivalent and 9-valent vaccine candidates with novel adjuvants, which are designed to adopt a two-shot regimen without compromising the efficacy/safety profile of vaccine candidates, and are potentially superior as compared to the commercialized products as they are all adopting three-shot regimen.

Having considered the Company's accumulation of phase III clinical trial sample size domestically in China and its decision to conduct the trial at clinical sites with higher HPV infection rate, it is expected that REC603 will be one of the first domestic vaccines of its kind to be approved and commercialized in China.

Cautionary Statement required under Rule 18A.08(3) of the Listing Rules: We cannot guarantee that we will ultimately develop or market our Core Product successfully. Shareholders and potential investors of our Company are advised to exercise due care when dealing in the Shares of our Company.

# REC601 - Phase I Stage HPV Bivalent (Type 16/18) Vaccine

The bivalent vaccine candidates are designed as HPV protection solutions for people with different affordability and have the potential to be included in the national vaccination regime in China and other jurisdictions. Due to the cost advantage of the HPV bivalent vaccine, it may become the mainstream vaccine for developing countries.

We are developing a bivalent HPV vaccine candidate, namely REC601, targeting HPV types 16 and 18, which are the main cause for a majority of cervical cancer cases. Currently, we have completed data evaluation and analysis on the phase I trial in China. The phase I trial data showed that REC601 has a favorable safety profile and an immunogenicity profile in healthy females aged 9 to 45. There was no vaccination-related grade 4 or higher AEs or SAEs. 30 days after the whole immunization, the positive rates of HPV types 16 and 18 antibodies reached 100.00%, and the negative population before immunization also reached positive conversion after the whole immunization (positive conversion rate was 100.00%). The HPV types 16 and 18 antibody levels also increased significantly: GMT of HPV type 16 antibody increased by 632.99 times and GMT of HPV type 18 antibody increased by 1,194.02 times compared with that before immunization. REC601 adopts a similar technical process line with the recombinant HPV 9-valent vaccine.

# REC602 - Phase I Stage HPV Bivalent (Type 6/11) Vaccine

We are also developing REC602, a bivalent HPV vaccine candidate targeting HPV 6/11. We have completed the Phase I trial in late 2022. REC602 adopts a similar technical process line with the recombinant HPV 9-valent vaccine.

# REC604a and REC604b - Early-Stage HPV Vaccines Formulated with Novel Adjuvant

Supported by our strong technology platforms, we are exploring opportunities to develop HPV vaccines formulated with novel adjuvant, namely REC604a and REC604b. Unlike the traditional alum adjuvant we are currently using, we are conducting early-stage development of nextgeneration HPV 9-valent and quadrivalent vaccines formulated with a novel self-developed adjuvant. Based on existing studies, compared to Merck's Gardasil, GSK's AS04-adjuvanted Cervarix has demonstrated strong cross-protection effectiveness with higher titers of neutralizing antibodies in clinical trials, suggesting that novel adjuvants can enhance the immunogenicity of HPV vaccines. As the introduction of novel adjuvant enhances immunogenicity profile of REC604a and REC604b, they are designed to adopt a two-shot regimen. The REC604a is equipped with the novel adjuvanted BFA04 independently developed by the Company. Preclinical studies have shown that the BFA04 adjuvant enhances the neutralizing antibodies by 7.7 times when compared with using an aluminum adjuvant. In an animal study conducted in mice, REC604a with a twoshot dosing has demonstrated its non-inferiority in terms of GMT level and immune persistence of serum neutralizing antibody as compared to Gardasil with a three-shot dosing. As of the date of this announcement, we have obtained the implied license for conducting clinical trials for REC604a in China. We plan to submit the IND application to the NMPA for REC604b in 2023.

# **COVID-19 Vaccines**

Since late 2019, the COVID-19 pandemic had caused a devastating social and economic impact in China and worldwide. COVID-19 has claimed more than 6 million lives reported by WHO Dashboard and is still circulating globally. Safe and effective vaccines are critical to the control of the COVID-19 pandemic. We are currently developing two COVID-19 vaccines.

# ReCOV - COVID-19 Vaccine Candidate under marketing application

Summary of Clinical Trial: For our recombinant COVID-19 vaccine, ReCOV, we have completed phase I clinical trial in New Zealand, and have completed Phase II clinical studies for basic immunization and sequential booster immunization in the Philippines and the United Arab Emirates. In November 2022, our ReCOV presented positive data from the Phase II clinical studies for basic immunization and sequential booster immunization in the Philippines and Phase II clinical studies for sequential booster immunization in the United Arab Emirates, and ReCOV completed the enrollment of subjects for international multi-center Phase III clinical trials. In particular, the Phase II clinical studies for sequential booster immunization in the Philippines have shown that, for subjects who have received vaccination with an inactivated vaccine for basic immunization, our ReCOV sequential booster can induce higher levels of neutralizing antibodies against Omicron variant BA.5, BA.2, BF.7 and BA.2.75 compared with the group administered with Pfizer's mRNA vaccine (with significant statistical differences). Based on the positive data above, we initiated the submission of product marketing application to the PRC regulatory authorities on a rolling basis in December 2022.

# Advantages of ReCOV: We believe our ReCOV has the following advantages:

Good broad-spectrum. ReCOV uses an optimized antigen, which is an NTD-RBD-foldon trimer, highly expressed by CHO cells, with a novel self-developed adjuvant BFA03. Our ReCOV can rapidly induce neutralizing antibodies and Th1 biased cellular immune responses. ReCOV has induced durable broad cross-neutralizing antibodies against prototype strain and multiple Omicron variants, showing favorable neutralizing effect compared with Pfizer's mRNA vaccines and Sinopharm's inactivated vaccines.

Good safety profile. Studies for basic immunization and sequential booster immunization have showed good safety profile of our ReCOV. There is an approximate TEAE rate between adult and elderly subject groups as well as the 20µg and the 40µg groups.

Significant accessibility advantage. Our ReCOV boasts fast-growing productivity, independent supply chain, and high preparation stability. Given self-developed adjuvants, high productivity and independent supply chain, the Company need not to rely on overseas manufacturer. Applying the disposable culture process for CHO cell, our ReCOV can achieve high yield and rapid expansion of production. It can be stored for at least six months at room temperature with quality unchanged and is expected to be stable for at least 24 months at  $2^{\circ}\text{C} - 8^{\circ}\text{C}$ .

Platform scalability. Leveraging our respiratory vaccine technology with novel adjuvant BFA03 and CHO expression system, the Company can quickly develop modified vaccines against variants or upper respiratory combination vaccines against COVID-19 or flu based on the first-generation of vaccine.

### R520A - Phase I mRNA COVID-19 vaccine

In August 2021, together with our business partners including Shenzhen Rhegen, we established a joint venture, namely Wuhan Recogen for the R&D and commercialization of mRNA vaccines. As the first step of this collaboration, we are developing R520A, a clinical research stage mRNA COVID-19 vaccine candidate, which specifically targets Omicron variant. R520A adopts a self-developed lyophilization technology. Through this approach, we can effectively sustain the physiochemical properties and bioactivity of mRNA-LNP and achieve long-term storage at 2°C – 8°C. We have been approved by the State Food and Drug Administration of the Philippines for clinical trials. As of the date of this announcement, the product has been approved for clinical trials in the Philippines, New Zealand and Hong Kong, China. The paper published in the international academic journal *Cell Discovery* (IF:38) with the title of "Lyophilized mRNA-lipid nanoparticle vaccines with long-term stability and high antigenicity against SARS-CoV-2" reported the lyophilized lipid nanoparticle vaccine against different variants of SARS-CoV-2.

# **Shingles Vaccine**

# REC610 - Recombinant Shingles Vaccine Candidate under Phase I Clinical Stage

In December 2022, we obtained a clinical trial approval in the Philippines for novel adjuvanted recombinant shingles vaccine, REC610, and the first batch of subject enrollment was completed in February 2023. This clinical study is a randomized, observer-blinded, GSK Shingrix® active-controlled phase I clinical trial to evaluate the safety and immunogenicity of REC610 in healthy adult subjects aged 40 and above. As of the date of this announcement, the first batch of subject enrollment for the phase I clinical trial in the Philippines has been successfully completed.

Shingles is an acute infectious skin disease caused by reactivation of latent varicella zoster virus (VZV) in the body. There is no specific medicine for shingles, and vaccine is an effective means of preventing shingles. According to research data on shingles vaccines that have been marketed around the world, the novel adjuvanted vaccine can provide stronger cellular immunity and protective efficacy as compared to live attenuated vaccines. REC610 is equipped with a novel adjuvant BFA01 independently developed by the Company, which can promote the production of high levels of VZV glycoprotein E (gE)-specific CD4+T cells and antibody. Preclinical studies have shown that REC610 has favorable immunogenicity and can induce high levels of gE-specific CD4+T cell responses and IgG antibody, and its immune response is non-inferior to the controlled vaccine Shingrix®.

# **TB Vaccine Pipeline**

# REC607 - Early-stage Virus Vectored Adult TB Vaccine Candidate

We have entered into a technology transfer agreement with Shanghai Public Health Clinical Center, pursuant which we obtained the know-how and patents with the exclusive global development rights of REC607, a virus vectored adult TB vaccine candidate. This program was recognized as a Major National Science and Technology Project (國家科技重大專項課題) in 2018. We are currently conducting preclinical R&D for our adult vector vaccine.

# REC606 - Early-stage Recombinant Adult TB Vaccine Candidate

We are also conducting early-stage study with respect to a recombinant adult TB vaccine, namely REC606. Our self-developed REC606 utilized both of the protein engineering platform and new adjuvant technology platform, both of which have the potential to result in better safety profile and immune response.

### **Other Disease Areas**

# REC617 - Early-stage Recombinant Influenza Quadrivalent Vaccine Candidate

We are developing REC617, an early-stage recombinant influenza quadrivalent vaccine and are developing novel adjuvants to enhance tolerability, immunogenicity, length of protection and cross-protection capability.

# REC605 - Early-stage HFMD Quadrivalent Vaccine Candidate

We are leveraging our protein engineering technology to develop a multi-valent HFMD vaccine, REC605, with increased serotype coverage of EV71, CA16, CA10 and CA6 and enhanced protection.

# **Our Technology Platforms**

We have developed three advanced technology platforms for novel adjuvant development, protein engineering and immunological evaluation. These platforms empower us to continue to discover and develop subunit vaccines that apply advancing technologies in our vaccine candidates.

## Novel adjuvant platform

Adjuvants are substances that are used in conjunction with antigens to assist in antigen presentation and enhance immune responses. Conventionally, only the alum adjuvant was widely used in vaccines for human use. Since the early 21st century, novel adjuvants have been widely applied in the vaccine industry gradually, and created vaccine products that can stimulate higher and broader immune response. At present, there are five novel adjuvants had been applied in FDA-approved vaccines for human use, namely AS01, AS03, AS04, CpG1018, and MF59, the components of which have been in the public domain for over 20 years. Through this platform, we are one of the few companies that have been able to develop adjuvant, benchmarking all of the above-mentioned FDA-approved adjuvants. This capability has enabled us to not rely on any particular adjuvant supplier. In addition, our platform also empowers us to discover and apply new adjuvants in the next generation vaccine candidates.

# Protein engineering platform

Our protein engineering platform utilizes a structure-based immunogen design approach to provide antigen optimization solutions for the development of subunit vaccines based on multidisciplinary studies. This platform enables us to rapidly target and prepare pathogen-derived antigens, to define the structural basis of antigenicity, to understand mechanisms of immune protection and to guide rational immunogen design, which are critical steps in our vaccine development. In addition, our protein engineering platform can elicit immune response in different expression systems, including E.coli, H. polymorpha, baculovirus and CHO cell expression systems, among others. With this diversified expression system toolbox, we are able to select and apply the most suitable expression systems in vaccine development. Through this platform, we are capable of rapidly advancing the development of our COVID-19 and HPV vaccine candidates.

### Immunological evaluation platform

To elucidate the mechanism of immune protection for emerging and re-emerging infectious diseases, immunological evaluation is a critical step in subunit vaccine discovery and development. With this platform, we are able to select the optimal antigen and adjuvant combination and in turn improve the immunogenicity profile of our candidates. The immunological evaluation process involves multiple disciplines, including immunology, biology, molecular biology and clinical chemistry. Our core scientific team began to build our immunological evaluation platform as early as 2004 and we became one of the first teams in China to have such a platform. With this platform, we are one of the first companies that can conduct pseudoviral neutralization, ELISPOT, and ICS tests in China, which have been used in the development of our vaccine candidates.

# **Research and Development**

R&D is crucial to our sustainable success. We are led by a core scientific team with over 20 years of experience in the research, development and commercialization of vaccine products, including working experience at the CDC in China. As of date of this announcement, our in-house R&D team consisted of over 100 talented personnel, most of them held masters or doctorate degrees in immunology, pathogen biology, clinical medicine or other related areas. Benefiting from our IPD System, our R&D team comprises four different product development teams, namely the vaccine innovation core, process research core, comprehensive R&D core and R&D quality core. Our R&D team is primarily located in our Beijing R&D center and our Taizhou R&D base, and is responsible for the full-cycle vaccine development.

Our IPD System lays a solid foundation for our R&D activities. The IPD System governs the entire life cycle of vaccine candidates. We conduct market demand analysis for our vaccine candidates at the early stage of vaccine development. Such analysis will serve as the basis of our vaccine development program to ensure our vaccine products can meet the market demand. In addition, under the IPD System, our R&D resources are allocated for the goals of each R&D project. As vaccine development involves a complex and multi-disciplinary process, for each vaccine development project we will assign a designated project manager and establish a product development team, consisting of employees from technology platforms and related departments including clinical and regulatory affairs, manufacturing, quality control and quality assurance. In addition, our management team is responsible for crucial decision-making and technical review at key points during the R&D process to ensure the R&D can satisfy our R&D protocol and the applicable legal and quality requirements. Empowered by the IPD System, we have been able to advance multiple vaccine development programs simultaneously.

We have developed three advanced technology platforms for novel adjuvant development, protein engineering and immunological evaluation. These platforms empower us to continue to discover and develop subunit vaccines that apply advanced technologies in our vaccine candidates. Our technology platforms have formed a "solid trifecta", creating synergies in antigen design optimization, the development and production of adjuvants, and the formulating of the combination of the optimal antigen-adjuvant. Supported by these platforms, we have developed several vaccine candidates. We are constantly upgrading our technology platforms to further enrich our R&D toolbox and we believe that our technology platforms will continue to drive our vaccine candidate development going forward.

For the year ended December 31, 2022, our total research and development costs amounted to RMB716.4 million and we had not capitalized any research and development costs for the same period.

# **Manufacturing and Commercialization**

Our R&D activities have primarily been conducted at our Beijing R&D center and Taizhou headquarters. Our Beijing R&D center is equipped with a pilot plant mainly for the pre-IND process development and has laboratories for vaccine R&D with a total GFA of approximately 4,000 sq.m. Our Taizhou headquarters R&D facility has a total GFA of approximately 3,800 sq.m. and four pilot plants, mainly for the manufacturing of our clinical trial samples and process development. Our R&D facilities can also support the manufacturing and development of novel adjuvants. Most of our vaccine candidates used in our clinical trials have been manufactured by our in-house manufacturing team, including our HPV vaccine pipeline.

In anticipation of the huge market demand of our clinical-stage vaccine candidates, we have started to prepare for the commercial manufacturing of our vaccine candidates. We are constructing our HPV vaccine manufacturing facility in Taizhou, Jiangsu province, the first phase of which has a designed peak annual capacity of 20 million doses of HPV 9-valent vaccines. In addition, we completed the construction of our GMP-standard manufacturing facility for ReCOV in Taizhou, Jiangsu province in November 2021 and obtained a vaccine manufacturing license issued by Jiangsu Medical Products Administration. The manufacturing facility has a total GFA of approximately 17,000 sq.m., and can also be used for the manufacturing of recombinant shingles vaccines. On April 9, 2022, the Company received the European Union (EU) Qualified Person Declaration issued by a Qualified Person (QP) for our ReCOV manufacturing facility in Taizhou.

In January 2022, the Company appointed Ms. Wang Jing, a senior expert in the industry, as the Chief Quality Officer, who was fully responsible for the quality-related work of the Group. Ms. Wang Jing has more than 20 years of experience in vaccine research and development, commercial production and quality management, and nearly 10 years of experience as a manager and quality authorized person of quality management department of vaccine production enterprises. The entry of Ms. Wang Jing will further strengthen the competitiveness of the Company's products and establish a quality system covering the entire life cycle of innovative vaccines. In May 2022, Ms. Feng Yanfei, a senior expert in the industry, joined the Company and served as the Chief Commercial Officer, and was fully responsible for the Company's global business development. Ms. Feng Yanfei has more than 20 years of working experience in the biopharmaceutical industry in China and the United States, covering product research and development, business development and international market management experience related to biotechnology and innovative drugs. The Company will further strengthen the close cooperation with international strategic partners, and accelerate the export of innovative vaccines such as HPV vaccines, so as to fill the huge and unmet global medical needs.

We have engaged third-party CMOs and manufacturers to produce vaccine samples for our clinical trials, aiming for an efficient and more cost-effective process. We have also adopted stringent procedures to ensure the facilities and production qualifications of our CMOs are in compliance with the relevant regulatory requirements and all of our CMOs are GMP certified. We selected a limited number of industry-leading third party CMOs based on their qualification, relevant expertise, manufacturing capacity, track record and the contract terms.

As of date of this announcement, we did not have any commercialized products. We have formulated clear commercialization strategy for our clinical-stage vaccine candidates, namely HPV vaccines, COVID-19 vaccines and recombinant shingles vaccines. In building sales channels and terminals for the commercialization of our vaccine candidates in domestic and international markets, we are currently building our sales team and international business development team. Our marketing team will be responsible for sales and academic promotion activities of the Company's products in China in the future, and our international business development team plans to enter into collaborations with foreign governments, MNCs, CSOs and international organizations to commercialize the Company's products overseas.

# **Intellectual Property**

As a company focusing on the research, development and commercialization of recombinant vaccine products, we believe intellectual property is crucial to our business. We actively seek patent protection for our vaccine candidates in China and major jurisdictions and file additional patent applications, when appropriate, to cover certain antigens, strains, proteins, formulations and production processes. We have developed a significant portfolio of intellectual property rights to protect our technologies and products. As of date of this announcement, we had registered 10 invention patents and had filed 74 patent applications (71 Chinese patent applications, and 3 PCT patent applications). For the year ended December 31, 2022, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that might be threatened or pending as claimant or respondent.

# **Employees and Remuneration**

As of December 31, 2022, the Group had 532 employees, all of whom were based in China. The total staff costs incurred by the Group (which are recorded as part of our administrative expenses, research and development costs and selling and distribution expenses) for the year ended December 31, 2022 were RMB213.2 million, as compared to RMB240.0 million for the year ended December 31, 2021. The remuneration package of our employees includes wages and other incentives, which are generally determined by their qualifications, industry experience, positions and performance. We make contributions to social insurance and housing provident funds in compliance with applicable PRC laws and regulations in all material respects. We also enter into standard confidentiality, intellectual property assignment and non-competition agreements with our key management and research and development staff, which typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for two years after the termination of his or her employment. Employees also sign acknowledgments regarding service inventions and discoveries made during the course of his or her employment.

# **Impact of the COVID-19 Pandemic**

As of date of this announcement, we had not experienced material disruptions in our operations and business development as a result of the COVID-19 pandemic. We had not experienced any early termination of our clinical trials or necessitated removal of subjects enrolled in the clinical trials due to the COVID-19 outbreak for the year ended December 31, 2022. We currently do not expect our supply chain will be materially and negatively impacted by COVID-19. Our major domestic suppliers had all resumed normal operations, and none of our overseas suppliers had reported any material disruption to their business operations as a result of COVID-19. We have employed various measures to mitigate the impact of COVID-19 on our business operations and clinical trials. We are also developing ReCOV, a recombinant COVID-19 vaccine candidate, with a novel adjuvant BFA03 benchmarking AS03. We initiated the rolling submission of product marketing application to China's competent regulator in December 2022.

### **Business Outlook**

Going forward, leveraging our strengths, we plan to implement the following strategies, which we believe will further strengthen our core competitive strengths and enable us to capture rising business opportunities:

- accelerate the R&D, clinical trial and commercialization of our vaccine candidates;
- continue to strengthen our R&D capabilities;
- refine our organization structure and human resource management to enhance our competitiveness; and
- advance our international strategy through "going-out" and "bringing-in" strategies.

Since December 31, 2022 and up to the date of this announcement, we have further advanced clinical trials for our vaccine candidates, and to the best of our knowledge, there is no change to the overall economic and market conditions in China or in the industry in which we operate that may have a material adverse effect to our business operations and financial position.

### FINANCIAL REVIEW

The following discussion is based on, and should be read in conjunction with, the financial information and the notes included elsewhere in this announcement.

# Analysis of our Key Items of our Results of Operations

## Other Income and Gains

Our other income and gains increased by 432.2% from RMB27.8 million for the year ended December 31, 2021 to RMB148.0 million for the year ended December 31, 2022, primarily because (i) our exchange gains arising from foreign currency transactions increased by RMB123.6 million from RMB-8.5 million for the year ended December 31, 2021 to RMB115.1 million for the year ended December 31, 2022; (ii) our bank interest income increased by RMB13.6 million from RMB10.4 million for the year ended December 31, 2021 to RMB24.0 million for the year ended December 31, 2022.

# Selling and Distribution Expenses

We recorded selling and distribution expenses for an amount of RMB8.7 million for the year ended December 31, 2022, which mainly represented the salaries incurred for our sales and marketing personnel in anticipation of the upcoming commercialization of ReCOV.

# Research and Development Costs

Our research and development costs increased by 51.5% from RMB473.0 million for the year ended December 31, 2021 to RMB716.4 million for the year ended December 31, 2022. Such increase in research and development costs resulted from the following:

- RMB255.9 million increase of clinical trial expenses from RMB113.5 million for the year ended December 31, 2021 to RMB369.4 million for the year ended December 31, 2022, primarily attributable to the expansion of scope of our ReCOV clinical trials and the steady progress of Phase III clinical trial for our Core Product REC603 since its initiation in June 2021;
- RMB12.9 million increase of depreciation and amortization from RMB23.4 million for the year ended December 31, 2021 to RMB36.3 million for the year ended December 31, 2022, primarily attributable to the increase in the purchase of instruments and equipment used in our R&D projects and the leasing of laboratories;
- RMB8.1 million increase of utilities and office expenses from RMB9.8 million for the year ended December 31, 2021 to RMB17.9 million for the year ended December 31, 2022, primarily attributable to the increase in R&D energy consumption such as utilities and steam as a result of the expansion of our clinical trials for ReCOV and HPV 9-valent vaccine.

# Administrative Expenses

Our administrative expenses increased from RMB143.0 million for the year ended December 31, 2021 to RMB155.3 million for the year ended December 31, 2022, primarily attributable to (i) an increase of RMB24.1 million in our advisory service fees for the year of 2022 compared with 2021; (ii) the increase of RMB12.8 million in our advertising expenses; and (iii) offset by the decrease of RMB22.5 million in our staff costs due to lower share-based payments as restricted shares of Lianyungang Ruiwenshibole Biotechnology Partnership (L.P.) which is the employee incentive platform had been amortized as one-off expenses in 2021.

# Other Expenses

Our other expenses decreased from RMB9.6 million for the year ended December 31, 2021 to RMB55,000 for the year ended December 31, 2022, primarily attributable to a decrease of RMB8.5 million in our exchange losses from the year ended December 31, 2021 since we incurred the exchange gains for the year ended December 31, 2022.

### Finance Costs

Our finance costs decreased by 93.7% from RMB56.3 million for the year ended December 31, 2021 to RMB3.5 million for the year ended December 31, 2022, primarily attributable to the decrease in interest on redemption liabilities on owners' capital.

### **Analysis of our Key Items of our Financial Position**

# Property, Plant and Equipment

Our property, plant and equipment primarily consisted of (i) leasehold improvements; (ii) plant and machinery; (iii) furniture and fixtures; (iv) computers and office equipment; (v) motor vehicles; and (vi) construction in progress. Our property, plant and equipment increased from RMB416.3 million as of December 31, 2021 to RMB558.7 million as of December 31, 2022, mainly due to the increase of construction in progress as we commenced the construction of our manufacturing facilities at No. 888 Yaocheng Avenue, Medical High-tech District, Taizhou City, Jiangsu Province, the PRC.

## Right-of-use Assets

Our right-of-use assets represent (i) leasehold land, representing the land use right of our manufacturing facility for our HPV vaccines with an original use right of 50 years; and (ii) leased properties, representing our leased manufacturing facility for ReCOV and our leased office buildings and laboratories. Our right-of-use assets increased from RMB55.3 million as of December 31, 2021 to RMB72.5 million as of December 31, 2022, primarily due to the increase in the leasing of our office space.

### Other Non-current Assets

Our other non-current assets mainly represent our time deposits and prepayment for purchase of property, plant and equipment. Our other non-current assets increased from RMB121.6 million as of December 31, 2021 to RMB215.6 million as of December 31, 2022, primarily due to the increase in prepayments for engineering and equipment as we commenced the construction of our manufacturing facilities.

# Prepayments, Other Receivables and Other Assets

Our prepayments, other receivables and other assets decreased from RMB88.5 million as of December 31, 2021 to RMB38.6 million as of December 31, 2022, primarily due to receipt of tax refund amounting to RMB85.4 million offset by newly accrual of RMB45.0 million in respect of value-added tax recoverable.

### Cash and Bank Balances

Our cash and bank balances increased from RMB1,182.6 million as of December 31, 2021 to RMB1,325.2 million as of December 31, 2022, primarily due to the proceeds from IPO financing of RMB670 million and an increase of RMB184 million in bank borrowings we received for the year and partially offset by an increase in investing activities for the commencement of the constructions of our manufacturing facilities.

# Trade Payables

Our trade payables increased from RMB16.8 million as of December 31, 2021 to RMB62.5 million as of December 31, 2022, primarily due to the increase in our procurement of reagents consumables and clinical services for our research and development activities.

# Other Payables and Accruals

Our other payables and accruals increased from RMB114.6 million as of December 31, 2021 to RMB244.7 million as of December 31, 2022, primarily due to (i) an increase in the clinical trial fee accrued from RMB29.2 million as at December 31, 2021 to RMB105.7 million as at December 31, 2022, which is in line with the progress of the research and development of our vaccine candidates; (ii) an increase in staff salaries, benefits and bonuses payable from RMB24.3 million as at December 31, 2021 to RMB43.1 million as at December 31, 2022, mainly in relation to our business expansion; (iii) an increase of RMB18.3 million in the purchase amount payable for ReCOV and HPV 9-valent industrialization-based equipment; and (iv) an increase in bid security of RMB25.4 million due to the purchase of industrialization-based equipment.

### Lease Liabilities

As of December 31, 2021 and December 31, 2022, we recorded lease liabilities of RMB26.7 million and RMB49.6 million, respectively.

## **Liquidity and Capital Resources**

Our primary uses of cash relate to the research and development of our vaccine candidates and the purchase of equipment and machinery. For the year ended December 31, 2022, we primarily funded our working capital requirement through equity financing and bank borrowings. We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. As our business develops and expands, we expect to generate more cash from our operating activities through commercialization of new vaccines. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of cash from operations, bank balances and cash and net proceeds from the Global Offering. As of December 31, 2022, our cash and bank balances amounted to RMB1,325.2 million. Out of the RMB1,325.2 million cash and bank balances as of December 31, 2022, RMB205.4 million (approximately 15.5%) was denominated in RMB, RMB701.5 million (approximately 52.9%) was denominated in U.S. dollars and RMB418.3 million (approximately 31.6%) was denominated in Hong Kong dollars.

### Net Current Assets

Our net current assets decreased from RMB1,155.3 million as of December 31, 2021 to RMB1,090.9 million as of December 31, 2022, primarily due to an increase of RMB130.1 million in other payables and accruals as compared to the previous year due to the increase in clinical research and development expenses accrued as well as the purchase of industrialization-based equipment for our ReCOV and HPV 9-valent vaccine.

# Charge on Asset

As of December 31, 2022, the Group had pledged the real estate located on the west side of Xiangtai Road and the north side of Yaocheng Avenue in Medical High-tech District, Taizhou, Jiangsu Province for a loan with a principal of RMB100 million (FY 2021: RMB50 million).

### Indebtedness and Financial Ratios

The total interest-bearing bank borrowings of the Group as of December 31, 2022 were RMB233.0 million. RMB1.4 million of the bank borrowings were current borrowings with a maturity date in 2023 and an effective rate of 3.45-3.90%. RMB231.6 million of the bank borrowings were non-current bank borrowings with a maturity date in 2024-2028 and an effective rate of 3.45-4.65%.

Our current ratio (calculated as current assets divided by current liabilities as of the same date) decreased from 9.3 as of December 31, 2021 to 4.3 as of December 31, 2022, mainly because our current liabilities had increased at a higher rate than our current assets. The increase in our current liabilities was primarily attributable to the increase in other payables and accruals, which is in line with the progress of research and development and industrialization of our vaccine candidates.

Our gearing ratio (calculated as total liabilities divided by total assets as of the same date) was 28.4% as of December 31, 2022 (as of December 31, 2021: 12.8%), as our total liabilities had increased at a higher rate than our total assets. The increase in our total liabilities was primarily due to the increase in total bank borrowings and other payables and accruals.

# Contingent Liabilities

As of December 31, 2022, we did not have any contingent liabilities.

# **Capital Expenditure and Contractual Commitments**

Our capital expenditure primarily includes (i) construction in progress; (ii) plant and machinery; (iii) leasehold improvements; (iv) motor vehicles; (v) computers and office equipment; and (vi) furniture and fixtures. Our capital expenditure increased from RMB276.5 million for the year ended December 31, 2021 to RMB296.7 million for the year ended December 31, 2022, mainly related to larger capital investment related to the construction of our new manufacturing facility and prepayments for the purchase of equipments for the year ended December 31, 2022 compared with 2021.

Our capital expenditure commitments decrease from RMB164.7 million as of December 31, 2021 to RMB68.9 million as of December 31, 2022, primarily because certain construction costs were settled in accordance with the relevant contractual terms.

As disclosed in the Prospectus, we plan to apply approximately HK\$88 million from the proceeds from the Global Offering (before exercise of over-allotment option) for constructing the HPV manufacturing facility in Taizhou. Save as disclosed above, the Group had no other material capital expenditure or investment plan as of date of this announcement.

# Significant Investments and Material Acquisitions and Disposals

Save as disclosed in this announcement, our Company had no other significant investments, material acquisitions and/or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2022.

# **Events after the Reporting Period**

References are made to the inside information announcement of the Company dated June 30, 2022, the circular dated July 29, 2022, the poll results announcement dated August 15, 2022, the announcement on the acceptance of application dated August 25, 2022, the announcement on the approval by the CSRC dated November 10, 2022, the announcement on the approval by the Stock Exchange dated December 5, 2022 and the completion announcement dated February 20, 2023 in relation to, among other things, the particulars of the Company's H Share full circulation application and the Company has completed the conversion of 222,498,569 Domestic Shares into H Shares, and the converted H Shares have been listed on the Stock Exchange since 9:00 a.m. on February 21, 2023. For details of the H Share full circulation, please refer to the above announcements and circular.

References are made to the inside information announcement of the Company dated October 31, 2022, the circular dated December 13, 2022, the poll results announcement dated December 28, 2022 and the announcement on the acceptance of application dated February 8, 2023 in relation to, among other things, the particulars of the Company's proposed issuance of Domestic Shares and the acceptance by the CSRC of the application materials. Issuance of Domestic Shares is subject to the satisfaction of a number of conditions (including the approval by the CSRC), and details of the issuance plan have not yet been finalized and further disclosure will be made by the Company in due course. For details of the issuance of Domestic Shares and relevant matters, please refer to the above announcements and circular.

Reference is made to the announcement of the Company dated March 20, 2023 in relation to the change of Directors, pursuant to which, Mr. Zhao Hui and Dr. Du Wei, due to change in personal work arrangements, resigned as non-executive Directors and members of the Remuneration and Appraisal Committee of the Board of the Company with effect from March 20, 2023. At the same time, the Board nominated Mr. Zhang Jiaxin as a non-executive Director of the Company and Ms. Chen Qingqing as an executive Director of the Company whose terms of office shall commence from the date of approval by the general meeting of the Company until the date of expiry of the term of the first session of the Board, which is subject to re-election. For details, please refer to the above announcement.

Save as disclosed in this announcement, we are not aware of any material subsequent events from the end of the Reporting Period to the date of this announcement.

### **Financial Risks**

We are exposed to a variety of financial risks, including interest risk, foreign currency risk, credit risk and liquidity risk as set out below. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

### **Interest risk**

The Group has no significant interest-bearing assets other than time deposits and cash and cash equivalents. The Group's interest rate risk arises from its borrowings, which are at variable rates and expose the Group to the risk of changes on market interest rates. The Group has not used any interest rate swaps to hedge its exposure to interest rate risk. The Group's exposure to the risk of changes in market interest rates relates primarily to the Group's debt obligations with a floating interest rate.

As at December 31, 2022, if interest rates on loans had been 50 basis points higher/lower with all other variables held constant, the loss before tax for the year ended December 31, 2022 would have been RMB670,000 (2021: RMB107,000) higher/lower, mainly as a result of higher/lower interest expense on loans.

# Foreign Currency Risk

We mainly operate in China and a majority of our transactions are settled in RMB, the functional currency of our Company's principal subsidiaries. The Group however has certain transactional currency exposure as a portion of our transactions are settled in U.S. dollars. The Group only trades with recognized and credit-worthy third parties. In addition, receivable balances are monitored on an ongoing basis and the Group's exposure to bad debts is not significant. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider hedging significant foreign exchange exposure should the need arise. The Group did not have significant foreign currency exposure from its operations as of December 31, 2022.

### Credit Risk

We generally trade only with recognized and creditworthy third parties. In addition, receivable balances are monitored on an ongoing basis and our exposure to bad debts is not significant. The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be "normal" when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be "doubtful".

As of December 31, 2022, cash and cash equivalents were deposited in banks of high quality without significant credit risk. The Directors are of the view that our exposure to credit risk arising from other receivables is not significant since counterparties to these financial assets have no history of default.

# Liquidity Risk

In the management of the liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by the management of our Group to allocate the working capital and mitigate the effects of fluctuations in cash flows. Our objective is to maintain a balance between continuity of funding and flexibility through the use of bank loans and other borrowings and lease liabilities. We aim to maintain sufficient cash and cash equivalents to meet our liquidity requirements.

# **Future Plans for Material Investments and Capital Assets**

Save as disclosed in this announcement, we did not have other plans for material investments and capital assets as of the date of this announcement.

# OTHER INFORMATION

# PURCHASE, SALE OR REDEMPTION OF OUR COMPANY'S SHARES

On December 28, 2022, the Company held an extraordinary general meeting and class meetings of shareholders, wherein we considered and approved the resolutions in relation to the issuance of Domestic Shares and its related matters (the "Issuance"). Accordingly, in order to further enhance the Company's overall competitiveness, increase the risk resistance capacity, supplement R&D funds for product pipelines under development and promote the steady and sound development of our business, the Company proposed to issue not more than 57,955,560 Domestic Shares to not more than 35 qualified domestic institutional investors with a nominal value of RMB1.00 each.

The proceeds from the Issuance are currently expected to be no less than HK\$640 million and will be used for the following purposes: (1) approximately 50% will be allocated for REC610, including the IND application, clinical trials, BLA submission, manufacturing facility construction and commercialization; (2) approximately 25% will be allocated for ReCOV, including the ongoing phase III clinical trials in Philippines, Nepal and Russia; and (3) approximately 25% will be allocated for the working capital and general corporate purposes.

On February 8, 2023, the Company received the CSRC Acceptance Notice of the Application for Administrative Permission (《中國證監會行政許可申請受理單》) issued by the CSRC, which indicated that our application materials for the issuance of Domestic Shares was accepted by the CSRC. The issuance of Domestic Shares is subject to certain conditions, including but not limited to the approval from the CSRC, and details of the issuance plan are not yet finalised, and further disclosure will be made by the Company in due course.

For details of the Issuance, please refer to the announcements of the Company dated October 31, 2022, December 28, 2022 and February 8, 2023 and the circular of the Company dated December 13, 2022.

Save as disclosed in this announcement, during the period from the Listing Date to December 31, 2022, neither our Company nor any of its subsidiaries purchased, sold or redeemed any listed securities of the Company.

### MODEL CODE FOR SECURITIES TRANSACTIONS

Our Company has adopted the Model Code since the Listing Date.

Specific enquiry has been made of all the Directors and Supervisors, and all Directors and Supervisors confirmed that they have complied with the Model Code for transactions in our Company's securities during the Reporting Period.

# **CORPORATE GOVERNANCE PRACTICES**

We strive to maintain high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability. Our Company has adopted the Code Provisions of the CG Code as the basis of our Company's corporate governance practices since the Listing Date.

Save as disclosed below, our Company has complied with all applicable Code Provisions as set out in the CG Code from the Listing Date up to the date of this announcement.

Under Code Provision C.2.1 of the CG Code, the roles of chairman and chief executive officer should be separate and should not be performed by the same individual. In view of Dr. Liu's experience, personal profile and his roles in our Company and that Dr. Liu has assumed the role of general manager of our Company since our commencement of business, the Board considers it beneficial to the business prospect and operational efficiency of our Company that Dr. Liu acts as the chairman of the Board and continues to act as the general manager of our Company.

While this will constitute a deviation from the code provision, the Board believes that this structure will not impair the balance of power and authority between the Board and the management of our Company, given that: (i) any decision to be made by our Board requires approval by at least a majority of our Directors; (ii) Dr. Liu and the other Directors are aware of and undertake to fulfil their fiduciary duties as Directors, which require, among other things, that they act for the benefits and in the best interests of our Company and will make decisions for our Company accordingly; and (iii) the balance of power and authority is ensured by the operations of the Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of our Company. Moreover, the overall strategic and other key business, financial, and operational policies of our Company are made collectively after thorough discussions by both the Board and senior management. The Board will continue to review the effectiveness of the corporate governance structure of our Company in order to assess whether separation of the roles of chairman of the Board and chief executive officer is necessary.

# USE OF PREVIOUS PROCEEDS AND CHANGE IN USE OF PROCEEDS

Our Company's H Shares were listed on the Stock Exchange on March 31, 2022. After exercise of over-allotment option on April 23, 2022, the net proceeds from the Global Offering amounted to approximately RMB669,714 thousand. As of December 31, 2022, the Company had utilized proceeds of approximately RMB210,607 thousand and unutilized proceeds amounted to approximately RMB459,107 thousand. Primarily used for item 1 "continuous optimization, development and commercialization of our HPV vaccine pipeline, including our Core Product, the recombinant HPV 9-valent vaccine REC603", item 2 "preclinical and clinical studies, registration of recombinant COVID-19 vaccines (recombinant COVID-19 vaccine, REC611 and mRNA COVID-19 vaccine, REC618)" and item 7 "working capital and general corporate purposes". The use of proceeds from the Global Offering as of December 31, 2022 had remained consistent with the use as disclosed in the Company's Prospectus.

In order to improve the efficiency of the use of proceeds, reduce financial expenses and align with the Company's strategic objectives, taking into account the sequence of the original use of proceeds, the Company intended to adjust the planning and proportion of the use of unutilized proceeds, by reallocating the proceeds originally planned for the use under item 4 "preclinical and clinical studies and registration of adult TB vaccines" and item 5 "preclinical and clinical studies and registration of recombinant HFMD vaccine, REC605, recombinant influenza quadrivalent vaccine, REC617 and other vaccines" to the use under item 2 "preclinical and clinical studies, registration of recombinant COVID-19 vaccines (recombinant COVID-19 vaccine, REC611 and mRNA COVID-19 vaccine, REC618)" and item 7 "working capital and general corporate purposes". Save as disclosed above, there were no other changes in use of proceeds. After careful consideration, the Board considered and approved the above change in use of proceeds on March 20, 2023.

The specific change proposals are as follows:

		Amount of net proceeds attributed to the proposed use (RMB thousand)	Utilized proceeds as of December 31, 2022 (RMB thousand)	Unutilized net proceeds as of December 31, 2022 (RMB thousand)	Use of net proceeds after reallocation (RMB thousand)
1	Continuous optimization, development and commercialization of our HPV vaccine pipeline, including our Core Product, the recombinant HPV 9-valent vaccine REC603, as follows:	316,633	49,704	266,929	266,929
(i)	The ongoing phase III clinical trial, registration, manufacturing and commercialization of our Core Product, REC603	302,393	42,431	259,962	259,962
(ii)	Preclinical and clinical studies for other HPV vaccine candidates, namely our recombinant HPV bivalent vaccine candidates REC601 and REC602 and adjuvanted second-generation HPV vaccine candidates REC604a and REC604b	14,240	7,273	6,967	6,967
2	Preclinical and clinical studies, registration of recombinant COVID-19 vaccines, namely recombinant COVID-19 vaccine, REC611, mRNA COVID-19 vaccine, REC618	118,798	109,850	8,948	43,604
3	Preclinical and clinical studies, registration of recombinant shingles vaccine, REC610	80,464	6,069	74,394	74,394
4	Preclinical and clinical studies, registration of adult TB vaccine	34,929	273	34,656	-

		Amount of net proceeds attributed to the proposed use (RMB thousand)	Utilized proceeds as of December 31, 2022 (RMB thousand)	Unutilized net proceeds as of December 31, 2022 (RMB thousand)	Use of net proceeds after reallocation (RMB thousand)
5	Preclinical and clinical studies, registration of recombinant HFMD vaccine, REC605; recombinant influenza quadrivalent vaccine, REC617 and other vaccines	26,087	3,630	22,457	-
(i)	Recombinant HFMD vaccine, REC605	9,025	91	8,934	_
(ii)	Recombinant influenza quadrivalent vaccine, REC617	6,970	6	6,964	-
(iii)	Other vaccines	10,092	3,533	6,558	_
6	Further enhancement of R&D capabilities and improvement in operating efficiencies, including:	44,513	9,303	35,209	35,209
(i)	Enhancement of technology platforms to support our ongoing needs	18,010	3,174	14,836	14,836
(ii)	Establishment of manufacturing and quality control system and upgrade of information technology infrastructure	26,503	6,129	20,373	20,373
7	Working capital and general corporate purposes	48,290	31,777	16,513	38,970
	Total	669,714	210,607	459,107	459,107

The Company has decided, after thorough consideration, to continue with the original expected timeline of utilizing the net proceeds from the Global Offering by the end of 2023.

The reallocation of the net proceeds is in line with the business strategies of the Company and is more favourable to the Company's long-term development, and there is no situation that damages the interests of Shareholders of the Company, especially the interests of small and medium-sized Shareholders, which is in the best interests of the Company and the Shareholders of the Company as a whole. The aforementioned change in use of net proceeds will not have any material adverse effect to the existing business and operations of the Company. The Company will continuously review the plan of use of unutilized net proceeds and revise the plan where necessary so as to cope with the changing market conditions and strive for better business performance of the Company.

Where the net proceeds are not immediately applied to the above purposes and to the extent permitted by the relevant law and regulations, so long as they are deemed to be in the best interests of our Company, we may hold such funds in short-term deposits with licensed banks or authorized financial institutions in Hong Kong.

# FINAL DIVIDENDS

The Board did not recommend the distribution of a final dividend for the year ended December 31, 2022 (FY 2021: Nil).

### REVIEW OF ANNUAL RESULTS

The combined financial statements of the Group for the year ended December 31, 2022 were audited by Ernst & Young. The Audit Committee of the Company has also reviewed the audited annual results of the Group for the year ended December 31, 2022. The figures in respect of the Group's results for the year ended December 31, 2022 as set out in this annual results announcement have been agreed by the auditor of the Company, Ernst & Young, to be consistent with the amounts set out in the Group's audited consolidated financial statements for the year ended December 31, 2022.

# ANNUAL GENERAL MEETING AND CLOSURE OF REGISTER OF MEMBERS OF H SHARES

The register of members of H Shares of the Company will be closed from Monday, May 8, 2023 to Thursday, May 11, 2023, both days inclusive, during which period no transfer of H Shares will be registered, in order to determine the holders of H Shares of the Company who are entitled to attend and vote at the forthcoming AGM to be held on Thursday, May 11, 2023. To be eligible to attend and vote at the AGM, all properly completed transfer documents accompanied by the relevant share certificates must be lodged with the Company's H Share Registrar, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong no later than 4:30 p.m. on Friday, May 5, 2023 for registration.

# PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

This annual results announcement will be published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.recbio.cn). The annual report of the Group for the year ended December 31, 2022 will be published on the websites of the Stock Exchange and the Company in accordance with the Listing Rules in due course.

# DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

# **Definitions**

"Annual General Meeting" or "AGM"	the annual general meeting of our Company proposed to be held on May 11, 2023;
"Articles of Association"	the articles of association of Jiangsu Recbio Technology Co., Ltd., as amended, supplemented or otherwise modified from time to time;
"Audit Committee"	the audit committee of our Company;
"Beijing ABZYMO"	Beijing ABZYMO Biosciences Co., Ltd. (北京安百勝生物科技有限公司), a limited liability company established in the PRC on March 7, 2011 and our wholly-owned subsidiary;
"Board"	the board of Directors of our Company;
"CDE"	the Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for review and approval of IND and BLA;
"CG Code"	the Corporate Governance Code contained in Appendix 14 to the Listing Rules, as amended, supplemented or otherwise modified from time to time;
"China" or "PRC"	the People's Republic of China, but for the purpose of the announcement and for geographical reference only and except where the context requires, references in the announcement to "China" and the "PRC" do not include Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan;
"Code Provision(s)"	the principles and code provisions set out in the CG Code;
"Companies Ordinance"	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time;

"Company" or "our Company"	Jiangsu Recbio Technology Co., Ltd. (江蘇瑞科生物技術股份有限公司), a joint stock company incorporated in the PRC with limited liability on May 25, 2021, or, where the context requires (as the case may be), its predecessor Jiangsu Rec-Biotechnology Co., Ltd. (江蘇瑞科生物技術有限公司), a limited liability company established in the PRC on May 18, 2012;
"Core Product"	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for the purpose of the announcement, our Core Product refers to REC603, a recombinant HPV 9-valent vaccine candidate;
"CSRC"	China Securities Regulatory Commission;
"Director(s)"	the director(s) of our Company;
"Domestic Share(s)"	ordinary shares in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in Renminbi by domestic investors;
"Dr. Liu"	Dr. Liu Yong, the executive Director and general manager of our Group;
"FDA"	the United States Food and Drug Administration;
"Global Offering"	the global offering of 30,854,500 H Shares (subject to over-allotment option) as described in the Prospectus;
"Group", "our Group", "we" or "us"	our Company and all of our subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of its present subsidiaries, the businesses operated by such subsidiaries or their predecessors (as the case may be);
"H Share(s)"	overseas listed foreign share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, which are listed on the Stock Exchange and traded in Hong Kong dollars;
"H Share Registrar"	Computershare Hong Kong Investor Services Limited;
"HK\$" or "Hong Kong dollars"	Hong Kong dollars, the lawful currency of Hong Kong;
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC;
"IASB"	International Accounting Standards Board;

the listing of our H Shares on the Stock Exchange;

the International Financial Reporting Standards, which as collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards and Interpretations issued by the IASB;

"IFRS"

"Listing"

"Listing Date" March 31, 2022, on which dealings in our H Shares first commenced on the Main Board of the Stock Exchange; "Listing Rules" the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time: "Main Board" the stock exchange (excluding the option market) operated by the Stock Exchange, which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange; "Model Code" the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules, as amended, supplemented or otherwise modified from time to time; the National Medical Products Administration of the PRC (國家 "NMPA" 藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局); "Prospectus" the prospectus issued by our Company on March 21, 2022 in relation to our Global Offering and Listing; "Remuneration and the remuneration and appraisal committee of our Company; Appraisal Committee" "Reporting Period" the year ended December 31, 2022; "RMB" or "Renminbi" Renminbi, the lawful currency of the PRC; "Share(s)" share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, comprising our Domestic Shares, Unlisted Foreign Shares and H Shares; "Shareholders" holders of our Shares: "Stock Exchange" the Stock Exchange of Hong Kong Limited; "subsidiary(ies)" has the meaning ascribed thereto in section 15 of the Companies Ordinance; "Supervisor(s)" supervisor(s) of our Company; "United States" or "U.S." the United States of America, its territories, its possessions and all areas subject to its jurisdiction;

"Unlisted Foreign Share(s)" ordinary share(s) issued by our Company with a nominal value of

RMB1.00 each and are held by foreign investors and are not listed

on any stock exchange;

"U.S. dollars" or "USD" United States dollars, the lawful currency of the United States;

"VAT" Value Added Tax;

"Wuhan Recogen" Wuhan Recogen Biotechnology Co., Ltd. (武漢瑞科吉生物科技

有限公司), a limited liability company established in the PRC on

September 28, 2021.

# **Glossary of Technical Terms**

"adjuvant" a substance that may be added to a vaccine to enhance the body's

immune response to an antigen;

"adjuvant system" formulations of classical adjuvants mixed with immunomodulators,

specifically adapted to the antigen and the target population;

"AE" adverse events, any untoward medical occurrences in a patient or

clinical investigation subject administered with a drug or other pharmaceutical product during clinical trials and which do not

necessarily have a causal relationship with the treatment;

"antigen" the substance that is capable of stimulating an immune response,

specifically activating lymphocytes, which are the body's infection-

fighting white blood cells;

"AS01" a liposome-based vaccine adjuvant system, which contains

3-O-desacyl-4'-monophosphoryl lipid A (MPL), as well as the

saponin QS-21;

"AS03" an adjuvant system composed of α-tocopherol, squalene and

polysorbate 80 in an oil-in-water emulsion;

"AS04" an adjuvant system composed of aluminum salt and monophosphoryl

lipid A (MPL), a clinically utilized TLR4 agonist;

"B cell(s)" a type of white blood cell that differ(s) from other lymphocytes like

T-cells by the presence of the BCR on the B-cell's outer surface.

Also known as B-lymphocytes;

"BLA" biologics license application;

"CD4" a transmembrane glycoprotein that is expressed as a single

polypeptide chain on the MHC class II-restricted T-cells;

"CD4+ T cells" a type of important T lymphocyte that helps coordinate the immune

response by stimulating other immune cells to fight infections;

"CD8+ T cells"	a type of important T lymphocytes for immune defense against intracellular pathogens, including viruses and bacteria, and for tumour surveillance;
"CDC"	Centre for Disease Control and Prevention;
"cervical cancer"	cancer that occurs in the cervix – the lower part of the uterus that connects to the vagina;
"CHO cell"	Chinese Hamsters Ovary Cell, which is widely used in biopharmaceutical industry to produce recombinant proteins;
"CMO(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;
"COVID-19"	Coronavirus Disease 2019, an infectious disease caused by the most recently discovered coronavirus, first reported in December 2019;
"DALYs"	the disability-adjusted life year, a measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death;
"E.coli"	Escherichia coli expression system, a expression system used in vaccine R&D and manufacturing;
"emulsion"	a mixture of two or more liquids that are normally immiscible (unmixable or unblendable) owing to liquid-liquid phase separation;
"epitopes"	part of an antigen that is recognized by the immune system, specifically by antibodies, B cells, or T cells;
"EV71"	Enterovirus 71, most EV71 infections commonly result in hand-footmouth disease (HFMD);
"GFA"	gross floor area;
"GMP"	good manufacturing practices;
"GMT"	geometric mean titers;
"H. polymorpha"	Hansenula polymorpha, a well-known model organism, which can utilize methanol as the carbon source and energy source, used widely for studying cellular, metabolic, and genetic issues, and used in vaccine industry for expression of recombinant proteins;
"HFMD"	hand-foot-mouth disease, a common infectious disease among infants and children, characterized by fever, sores in the mouth and

a rash with blisters on hands, feet and also buttocks;

"HIV"	human immunodeficiency virus, which attacks cells that help the body fight infection, making a person more vulnerable to other infections and diseases and spreading by contact with certain bodily fluids of an infected person;
"HPV"	human papillomavirus, persistent infection of high-risk types can cause cervical cancer;
"HPV 9-valent vaccine"	a vaccine that can help protect individuals against the infections and diseases caused by nine types of HPV;
"HPV bivalent vaccine"	vaccines that can prevent infections of two HPV types;
"HPV quadrivalent vaccine"	vaccines that can prevent infections of four HPV types;
"immune response"	the process by which the body is stimulated by antigens;
"immunogenicity"	the ability of an antigen to provoke immune response;
"IND"	investigational new drug or investigational new drug application;
"influenza" or "flu"	highly infectious respiratory diseases caused by influenza viruses. It is characterised by sudden onset of high fever, aching muscles, headache, fatigue and a hacking cough. Serious outcome of influenza can result in hospitalization or death;
"IPD"	Integrated Product Development, a structure of work and best practices that causes people to work together more effectively with better communications and metrics that connect the entire value chain which is the standard of the matrix management mode;
"MF59"	an adjuvant system that uses a derivative of shark liver oil called squalene;
"MoA"	mechanism of actions;
"mRNA"	messenger ribonucleic acid, a single-stranded molecule of RNA that corresponds to the genetic sequence of a gene, and is read by a ribosome in the process of synthesizing a protein;
"neutralizing antibodies" or "NAb"	an antibody that is responsible for defending cells from pathogens, which are organisms that cause disease;
"NTD"	N-terminal domain, a region of the protein's polypeptide chain located at the start of the protein that is self-stabilizing and that folds independently from the rest;
"Omicron variant"	variant of lineage B.1.1.529 of SARS-Co-2, the virus that causes COVID-19;

"OPTI" the management philosophy adopted by our Company, which referred to Opportunity, Prudence, Technology and Intellectual Property; "pathogens" a bacteria, virus, or other microorganism that can cause disease; "OS-21" a purified plant extract used as a vaccine adjuvant; "R&D" research and development; "RBD" receptor binding domain, a key part of a virus located on its "spike" protein that allows it to dock to body receptors to gain entry into cells and lead to infection: "SAE" serious adverse events, any untoward medical occurrence in human drug trials that at any dose: results in death; is life threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/ incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage; "SARS-CoV-2" severe acute respiratory syndrome coronavirus 2, the strain of coronavirus that causes COVID-19; "shingles" a viral infection that causes a painful rash; "T cell(s)" cell(s) that originate in the thymus, mature in the periphery, become activated in the spleen/nodes if their T-cell receptors bind to an antigen presented by an MHC molecule and they receive additional costimulation signals driving them to acquire killing (mainly CD8+ T cells) or supporting (mainly CD4+ T cells) functions; "TB" tuberculosis, an infection caused by Mycobacterium tuberculosis that primarily affects the lungs; "TLR4" a receptor for lipopolysaccharide (LPS), which has a pivotal role in the regulation of immune responses to infection; "tolerability" the degree to which overt AEs of a drug can be tolerated by a patient. Tolerability of a particular drug can be discussed in a general sense, or it can be a quantifiable measurement as part of a clinical study; "varicella" an acute infectious disease caused by the first infection of varicella zoster virus;

World Health Organization.

"VLPs"

"WHO"

virus-like particles, are molecules that closely resemble viruses;

Certain amounts and percentage figures included in this announcement have been subject to rounding adjustments.

For ease of reference, the names of the PRC laws and regulations, governmental authorities, institutions, natural persons or other entities (including certain of our subsidiaries) have been included in this announcement in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail. English translations of official Chinese names are for identification purpose only.

By order of the Board

Jiangsu Recbio Technology Co., Ltd.

Dr. Liu Yong

Chairman

Jiangsu Province, the PRC, March 20, 2023

As at the date of this announcement, the Board comprises Dr. Liu Yong as the chairman of the Board and an executive Director, Dr. Chen Jianping and Mr. Li Bu as executive Directors, Dr. Hong Kunxue, Dr. Zhou Hongbin and Dr. Feng Tao as non-executive Directors, and Mr. Liang Guodong, Dr. Xia Lijun, Professor Gao Feng and Professor Yuen Ming Fai as independent non-executive Directors.