

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**SinoMab BioScience Limited**

**中國抗體製藥有限公司**

*(Incorporated in Hong Kong with limited liability)*

**(Stock code: 3681)**

**ANNUAL RESULTS ANNOUNCEMENT FOR  
THE YEAR ENDED 31 DECEMBER 2021  
AND CHANGE IN USE OF PROCEEDS**

The board (the “**Board**”) of directors (the “**Directors**”) of SinoMab BioScience Limited (中國抗體製藥有限公司) (the “**Company**” together with its subsidiaries, the “**Group**”) hereby announces the audited consolidated annual results of the Group for the year ended 31 December 2021 (the “**Reporting Period**”), together with the comparative figures of the year ended 31 December 2020. The consolidated financial statements of the Group for the Reporting Period, including the accounting principles and practices adopted by the Group, have been reviewed by the audit committee of the Company (the “**Audit Committee**”) and audited by the Company’s auditor. Unless otherwise specified, figures in this announcement are prepared under the Hong Kong Financial Reporting Standards (“**HKFRSs**”).

In this announcement, “we”, “us” and “our” refer to the Company and where the context otherwise requires, the Group.

**BUSINESS HIGHLIGHTS**

The Board is excited to announce that, during the Reporting Period, we achieved significant progress with respect to the Group’s clinical trial programs, pipeline development, and preparation of commercialisation, including the following:

- Our flagship product Suciraslimab (SM03), (*anti-CD22 monoclonal antibody*) — As at the end of the Reporting Period, the Phase III clinical trial for rheumatoid arthritis (“**RA**”) has completed its enrollment of 530 patients, which is beyond the original target of 510 patients. The primary analysis readout is expected in the third quarter of 2022. We plan to file our New Drug Application (“**NDA**”) with the National Medical Products Administration of the People’s Republic of China (“**PRC**”) (the “**NMPA**”) in the first half of 2023 and expect to commercialize Suciraslimab by the second half of 2023.

- Our key product SN1011, (*BTK Inhibitor*) — Following the approval of Investigational New Drug (IND) application for Pemphigus and systemic lupus erythematosus (SLE), the Company is initiating a Phase II clinical study targeting Pemphigus (for both pemphigus vulgaris (PV) and pemphigus foliaceus (PF)) in China in the third quarter of 2022. In addition, a new IND submission in multiple sclerosis (MS) was submitted to the Center for Drug Evaluation (CDE) of the NMPA in January 2022, and approval is expected to be granted in the second quarter of 2022.
- Another key product SM17, (*Humanised Anti-IL17RB*) — IND application was submitted and accepted by the U.S. Food and Drug Administration (FDA) in February 2022 and was subsequently approved by the FDA in March 2022. The First-In-Human (FIH) phase I clinical study is expected to commence in the U.S. in the first quarter of 2022 at the earliest.
- Collaboration — A license agreement was entered into by the Company in September 2021 to out-license the right to develop and commercialize SN1011 globally for the treatment of renal diseases. The Company retains all other immunological rights for all indications (other than immunological related renal diseases) relating to SN1011 and will continue its research and development, including a phase II study currently initiating in China. Under the License Agreement, the Company has received in 2021 US\$4 million upfront and is entitled to up to an aggregate of US\$183 million in total development and sales milestones.
- Commercial Production Base — Topping-out ceremony for our Suzhou campus, located at the Suzhou Dushu Lake High Education Town, China, was held in December 2021. Phase I development with a production capacity of 6,000 litres is expected to come into operation in 2023. Upon completion of the new Suzhou campus, the production capacity of the production base would be over 32,000 litres.
- Exploring novel drug targets identification — a research, development and commercialization agreement was entered into between the Company and D2M in July 2020 for a long-term collaboration for the identification of novel drug targets. Under the collaboration, the Company is entitled to conduct subsequent researches, development and commercialisation with regards to qualified drug targets which are chosen by the Company from the original results of D2M's target identification works according to a prioritised target-selection mechanism.

## FINANCIAL HIGHLIGHTS

- Loss for the year increased by RMB165.6 million from RMB122.6 million for the year ended 31 December 2020 to RMB288.2 million for the year ended 31 December 2021, which was mainly due to (i) the increase in costs of business development in research and development (“**R&D**”) of approximately RMB95.7 million; and (ii) the increase in administrative expenses of approximately RMB61.4 million, mainly due to recognition of a non-cash share-based payment of approximately RMB62.9 million under the Company’s restricted share units scheme (the “**RSU Scheme**”) in the Reporting Period (2020: RMB34.9 million).
- Net cash used in investing activities for the Reporting Period was approximately RMB137.7 million, which was mainly due to (i) the capital expenditures of subsidiaries in Suzhou and Hainan of approximately RMB211.3 million to enhance the Group’s production capacity; (ii) an investment in D2M Biotherapeutics Limited (“**D2M**”), of approximately RMB16.2 million; and offset by (iii) the proceeds from the disposal of China Healthcare Fund Segregated Portfolio (“**China Healthcare Fund**”) of approximately RMB92.0 million.
- The Board does not recommend payment of a final dividend for the Reporting Period.

## BUSINESS OVERVIEW

The year 2021 is still a challenging year. Since the outbreak of COVID-19 at the end of 2019, new variants including Delta and Omicron, have wreaked havoc around the world. Hong Kong, Mainland China and other parts of the world have been trying to control the pandemic. All staff of the Company remained committed to working with a professional and responsible attitude and made contributions to the Company's business activities and research and development (“**R&D**”) work, achieving fruitful pharmaceutical R&D attainments and breakthroughs.

Our flagship product Suciraslimab (SM03) for treating rheumatoid arthritis (“**RA**”) has completed the enrolment of 530 patients for Phase III clinical trial in China on 31 December 2021, which is higher than the targeted enrolment of 510 patients. The Phase III clinical trial is a multi-centre, randomized, double-blind, placebo-controlled, parallel group study to confirm the clinical efficacy and long-term safety in active RA patients receiving methotrexate (MTX). The primary analysis readout is expected in the third quarter of 2022. The efficacy and safety of SM03 has been evaluated in a phase II clinical study in moderate-to-severely active RA patients and has achieved desirable results. Both high-dosage group and low-dosage group met the primary endpoint and showed significantly better performance than the placebo group. We plan to submit the New Drug Application (“**NDA**”) to the National Medical Products Administration (“**NMPA**”) in the first half of 2023 and expect to realise the commercialization of SM03 in the second half of 2023. In the meantime, we will promote the clinical study on the treatment of systemic lupus erythematosus (“**SLE**”), Sjogren's syndrome (“**SS**”) and other indications with SM03, expanding the scope of SM03 to fulfil unmet medical needs. The Phase II clinical study for SLE is expected to be initiated in China in the second half of 2022.

The R&D of drug candidate SN1011, our key product and third-generation covalent reversible Bruton's tyrosine kinase (“**BTK**”) inhibitor, has also achieved progresses. The Phase I study (first-in-human clinical trial) of SN1011 was conducted in Australia and China in 2019 and completed in July 2021, which has demonstrated good safety and pharmacokinetics profile. Following the approval of Investigational New Drug (“**IND**”) applications of SN1011 for SLE and Pemphigus by the NMPA on 27 August 2020 and 23 June 2021 respectively, we will launch the Phase II clinical study for pemphigus (for both pemphigus vulgaris (“**PV**”) and pemphigus foliaceus (“**PF**”)) in China in the third quarter of 2022. Besides, after the Reporting Period, the IND application of SN1011 for multiple sclerosis (“**MS**”) has been accepted by the Center for Drug Evaluation, NMPA on 28 January 2022, and the approval is expected in the second quarter of 2022. We plan to initiate the global Phase II clinical trial for multiple sclerosis (MS) in China and the United States in the third quarter of 2022.

We have submitted the IND application for the Company's First-in-Class asthma therapeutic product SM17 (humanised anti-IL17RB monoclonal antibody for injection) to the U.S. Food and Drug Administration ("FDA"), and the application has been approved. SM17, the world's first monoclonal antibodies targeting IL17BR co-developed by us and LifeArc (a medical research charity based in the United Kingdom), covers a wide range of indications, including indications with large market volumes such as asthma and diseases with high mortality rates such as idiopathic pulmonary fibrosis, and potentially displaying differential clinical benefits over other currently available drugs in the market. We plan to initiate the First-In-Human (FIH) clinical study in the United States in the first quarter of 2022 at the earliest.

Another drug candidate, SM06, is a second-generation humanised anti-CD22 antibody derived from SM03 that works with the same mechanism of action. We believe that SM06 will be less immunogenic and thus more suitable for treating chronic diseases requiring long-term administration, such as SLE, RA and other immunological diseases. We are currently in the process of optimising production for SM06, collecting process and pre-clinical data for speedy filing of SM06 in the U.S. for global clinical studies. We expect to submit the first IND application for SM06 in 2022 at the earliest.

Our innovative R&D strength and the market prospects of drug candidates also bring us greater financial support. In September 2021, we entered into the first license agreement to grant the right of developing and commercializing SN1011, a major product of the Company, in the field of treatment of renal diseases worldwide, which manifests the potential of SN1011 through industrial recognition. The Company has received US\$4 million upfront payment in 2021 under the License Agreement and is entitled to up to US\$183 million development and sales milestone payments. We will continue to seek more cooperation opportunities to further diversify our portfolio of drug candidates and expand our global reach.

We have two production bases that can provide the foundation for the stable clinical and commercial productions of portfolio product candidates. We have been constructing our Suzhou plant with a production capacity of 32,000 litres in the Suzhou Dushu Lake High Education Town, China. The headquarters together with the plant at the same site has a total area of about 75,000 sq.m., which consists of a manufacturing plant, a pilot plant an R&D centre, a quality control facility, a clinical study centre and an administration building. The construction of a pilot facility, including administrative offices, process development and quality control laboratories and R&D laboratories in the Suzhou base was completed in 2019. The administration facilities have been in operation since late-2020 to support ongoing and new product development projects. In alignment with the Company's development plan of expanding R&D and product development capacities, we have established a new R&D and CMC laboratories in the Suzhou base, which is commissioned with a full set of equipment and has been put into service in December 2021. We also have a production base with a capacity of 1,200 litres in Haikou, the total operation area of which has been expanded from approximately 4,526 sq.m. to

approximately 19,163 sq.m. The base consists of a clean area for processing, a controlled-not-classified (CNC) area for supporting activities, utility rooms, quality control laboratories, warehouses and administrative offices, which can satisfy the clinical and preliminary marketing requirements.

We have developed a platform across the whole industry chain, which consists of target identification, drug candidate development, clinical trials, pre-clinical research, clinical production, quality control, quality assurance, regulatory approval and commercial-scale production. Leveraging our full-spectrum platform that leads in the Greater China region, plus the constantly expanding R&D and production capacities in Hainan and Suzhou, we manage the product development programs more effectively, resulting in improved efficiency towards expanded R&D activities, speedy clinical studies and commercialization of antibody drugs, reinforcing our commitment to growing into an innovation-driven biopharmaceutical company with strengths in R&D, production and commercialization of diversified products for sustainable growth and development.

## **OUTLOOK**

In the macro environment where the world is fighting the COVID-19, public health becomes the focus of the world, and the pharmaceutical sector receives much attention in the capital market. In February 2022, nine departments, namely the Ministry of Industry and Information Technology, the National Development and Reform Commission, the Ministry of Science and Technology, the Ministry of Commerce, the National Health Commission, the Ministry of Emergency Management, the National Healthcare Security Administration, the NMPA and the National Administration of Traditional Chinese Medicine, jointly released the Plan for Development of Pharmaceutical Industry over the 14th Five-Year Plan Period. The document sets the goals of strengthening the innovation capacity, improving industry chain and supply chain, improving the supply support mechanism, upgrading the manufacturing level, intensifying the industrial upgrading and enhancing the international competitiveness. In view of the favourable factors of international environment and national policies, we expect a promising prospect. We will focus on our vision of independent innovation, advance the novel drug target identification, further expand the product portfolio, develop greater scope of indications for drug candidates and strengthen product R&D, production and commercialization capacities, hoping to grow into a global leader in novel treatments of immunological diseases who continuously contributes towards the pharmaceutical field.



## MANAGEMENT DISCUSSION AND ANALYSIS

### BUSINESS REVIEW

The Group is principally engaged in research and development of pharmaceutical products.

The operating performance and the progress of the Group's clinical projects during the year under review and future prospects are contained in the sections headed "Business Overview" and "Outlook" above as well as in this sub-section.

The Group has no immediate plan for material investments or capital assets, other than as disclosed in the above section headed "Business Overview" and this sub-section.

A brief review on the business operation and clinical projects currently undertaken by the Group is set out below.

#### Overview

We are the first Hong Kong-based listed biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases, primarily monoclonal antibody ("mAb")-based biologics. Headquartered in Hong Kong, we strive to become a leading global biopharmaceutical company for the development of novel drugs to fulfil unmet medical needs through our Hong Kong-based R&D and innovation, and PRC-based manufacturing capabilities. We have been dedicated to R&D since our inception, and have built a pipeline of mAb-based biologics and new chemical entities ("NCE") addressing indications against a plethora of immunological diseases.

Our flagship product, SM03 (Suciraslimab), is a potential global first-in target mAb for the treatment of rheumatoid arthritis ("RA") and potentially for the treatment of other immunological diseases such as systemic lupus erythematosus ("SLE"), Sjogren's syndrome ("SS") as well as non-Hodgkin's lymphoma ("NHL"), and other indications. The phase III clinical trial in RA has completed on 31 December 2021 its enrollment of 530 patients, which is beyond the original target of 510 patients. The primary analysis readout is expected in the third quarter of 2022. We plan to file our New Drug Application ("NDA") with the National Medical Products Administration of the People's Republic of China ("PRC") (the "NMPA") in the first half of 2023 and expect to commercialize Suciraslimab by the second half of 2023.

Our key product, SN1011, is a third generation covalent reversible Bruton’s tyrosine kinase (“**BTK**”) inhibitor, and was designed for high selectivity and superior efficacy for potentially the long-term treatment of patients with chronic immunological disorders. A phase I study has been completed in China and Australia, and demonstrated good Pharmacokinetics (“**PK**”) and safety profile. A phase II study in pemphigus vulgaris (“**PV**”) is scheduled to be initiated in the third quarter of 2022. An IND application in multiple sclerosis (“**MS**”) was submitted and accepted by the Center for Drug Evaluation (the “**CDE**”) of the NMPA in January 2022. The Company is planning a parallel IND submission for multiple sclerosis (MS) in the U.S. in the second quarter of 2022, and subsequent initiation of a global phase II trial in the third quarter of 2022. In addition to the above indications, the compound has also received regulatory approval for conducting clinical studies on systemic lupus erythematosus (SLE) in China.

Another key product, SM17, is a first-in-class and first-in-target humanised anti-IL 17RB antibody. The IND application was submitted and accepted by the U.S. Food and Drug Administration (“**FDA**”) in February 2022 and was subsequently approved by the FDA in March 2022. The First-in-Human (FIH) study is expected to start by the first quarter of 2022 at the earliest. The compound has the potential for treating asthma, atopic dermatitis, and idiopathic pulmonary fibrosis.

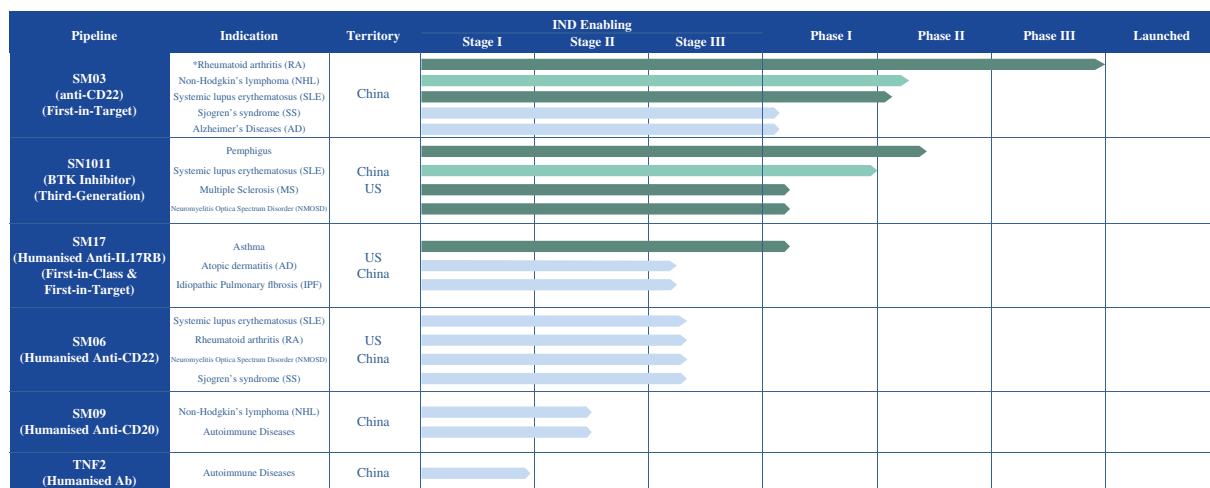
Our other drug candidate, SM06, is a second-generation humanised anti-CD22 antibody derived from SM03 (Suciraslimab) with the same mechanism of action. The compound is at IND enabling stage for U.S. submission, and currently in the process of optimization for clinical studies by the first quarter of 2023.

Our vision is to become a global leader in the innovation of therapeutics for immunological and other debilitating diseases.

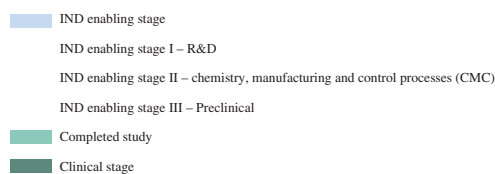


## Progress of clinical projects

### Product pipeline



\* RA phase III completed recruitment in December 2021



### Flagship product

#### SM03 (Suciraslimab)

Our self-developed SM03 (Suciraslimab) is a potential first-in-target anti-CD22 mAb for the treatment of rheumatoid arthritis (RA) and potentially for other immunological diseases such as systemic lupus erythematosus (SLE), Sjogren's syndrome (SS) as well as non-Hodgkin's lymphoma (NHL). Suciraslimab adopts a novel mechanism of action, which differentiates itself from the current treatments available in the market. Suciraslimab for RA is currently in Phase III clinical trials in China, and we expect it to be our first commercially available drug candidate.

We plan to rapidly advance the development of Suciraslimab. On 31 December 2021, Suciraslimab (SM03) phase III clinical trial for RA has completed its enrollment of 530 patients, which is beyond the original target of 510 patients. The Phase III clinical trial is a multi-center, randomized, double-blind, placebo-controlled, parallel group study to confirm the clinical efficacy and long-term safety in active RA patients receiving methotrexate (MTX). The efficacy and safety of Suciraslimab was previously evaluated in a phase II clinical study in moderate-to-severely active RA patients. The study results were published recently and shown that Suciraslimab at a dose of 600 mg with 4 and 6 infusions respectively, were both efficacious and well-tolerated throughout the 24 weeks of treatment when compared with the placebo group. Suciraslimab was effective in suppressing disease activity and alleviates symptoms of moderate-to-severely active RA patients receiving stable doses of background MTX. The primary analysis readout for Phase III studies is expected in the third quarter of 2022. We plan to file our New Drug Application (“NDA”) with the National Medical Products Administration of the People’s Republic of China (“PRC”) (the “NMPA”) in the first half of 2023 and expect to commercialize Suciraslimab by the second half of 2023. In addition to our efforts to develop Suciraslimab as a therapeutic for RA, we will advance Suciraslimab clinical trials for SLE, SS and other indications to broaden the therapeutic uses of Suciraslimab for addressing other unmet medical needs. We expect to initiate Phase II clinical study for SLE in China in the second half of 2022.

### ***Key products***

#### *SN1011*

SN1011 is a third generation, covalent reversible Bruton’s tyrosine kinase (“BTK”) inhibitor designed for higher selectivity, superior efficacy and improved safety for the long-term treatment of systemic lupus erythematosus (SLE), pemphigus vulgaris (PV), multiple sclerosis (MS), and other rheumatology or neuro-immunological diseases. SN1011 differentiates from existing BTK inhibitors currently available in the market, such as Ibrutinib, in terms of mechanism of action, affinity, selectivity and safety.

The phase I study (First-in-Human) was conducted in Australia and China in 2019, and was completed in July 2021. The study has demonstrated good safety and Pharmacokinetics (“PK”) profile. An IND application of SN1011 for the treatment of Pemphigus was also approved by the NMPA on 23 June 2021. Following SN1011 IND approval for Pemphigus and SLE, the Company is initiating Phase II clinical study targeting Pemphigus (for both pemphigus vulgaris (PV) and pemphigus foliaceus (PF)) in China. A phase II study in PV is scheduled to be initiated in the third quarter of 2022. In addition, a new IND submission in multiple sclerosis (MS) was submitted to the NMPA CDE in January 2022, and approval is expected to be granted in the second quarter of 2022. The Company is planning a parallel IND submission for multiple sclerosis (MS) in the U.S. in the second quarter of 2022, and subsequent initiation of a global phase II trial in the third quarter of 2022. In addition to the above indications, the

compound has also received regulatory approval for conducting clinical studies on SLE in China. Please also refer to the Company's announcements dated 14 November 2019, 29 January 2020, 29 June 2020, 1 September 2020, 15 January 2021, 24 June 2021, 23 July 2021 and 7 February 2022 for further information about the latest R&D progress of SN1011.

### *SM17*

SM17 is developed to treat eosinophilic asthma via blockage of IL25 signalling via the IL17RB receptor expressed on specific subgroup of lymphoid cells known as ILC2. The antibody is specific to IL17RB, which is found to be significantly upregulated in biopsy tissues of asthmatic patients. When evaluated in a murine-based Ovalbumin (OVA)-induced Allergic Asthma Model, blockage of receptor signaling by the antibody enhanced protection against airways resistance, and significantly reduced cell infiltration into the lungs and serum levels of antigen specific immunoglobulin E (IgE). This potential first-in-class and first-in-target antibody was further humanized by the Group's international partner, LifeArc (a medical research charity based in the United Kingdom), using their proprietary humanisation technology. The antibody is also found to exhibit other therapeutic potential, including other T2 helper cell pathway involved allergic diseases, such as atopic dermatitis (“**AD**”), type II ulcerative colitis and idiopathic pulmonary fibrosis (“**IPF**”).

The IND application was submitted and accepted by the FDA in February 2022 and was subsequently approved by the FDA in March 2022. The First-in-Human (FIH) phase I clinical study is expected to commence in the U.S. in the first quarter of 2022 at the earliest. The phase I clinical study consists of SAD (single ascending dose) and MAD (multiple ascending doses) in healthy volunteers to evaluate the PK/pharmacodynamics (“**PD**”) parameters and safety profile. Please also refer to the Company's announcements dated 16 February 2022 and 14 March 2022 for further information about the latest R&D progress of SM17.

### *Other drug candidates*

#### *SM06*

SM06 is a second-generation anti-CD22 antibody that is humanised using our proprietary framework-patching technology. SM06 is a humanised version of Suciraslimab (SM03) with the same mechanism of action. It is contemplated to be a less immunogenic and more human-like antibody with potentially improved safety profiles. We believe that SM06 will be less immunogenic and thus more suitable for treating chronic diseases requiring long-term administration, such as systemic lupus erythematosus (SLE), rheumatoid arthritis (RA) and other immunological diseases. We are currently in the process of optimising chemistry, manufacturing and control processes (CMC) for SM06, collecting process and pre-clinical data for speedy filing of SM06 in the U.S. for global clinical studies. We expect to submit the first IND application for SM06 in the U.S. in 2022 at the earliest.

## *SM09*

SM09 is a framework-patched (humanised) anti-CD20 antibody that targets an epitope different from that of other market-approved anti-CD20 antibodies such as rituximab, obinutuzumab and ofatumumab for the treatment of NHL and other auto-immune disease with significant unmet medical needs.

## *TNF2*

TNF2 is a humanised version of infliximab for the treatment of rheumatological diseases with characteristic elevated level of TNF- $\alpha$ . The antibody blocks binding of TNF- $\alpha$  onto its receptors with affinity and specificity comparable to infliximab, and efficiently inhibits TNF- $\alpha$  induced death of L929 cell, which is a murine fibroblast cell line.

## **Collaboration**

On 16 September 2021, a license agreement was entered into between the Company, Suzhou Sinovent Pharmaceutical Technology Co., Ltd.\* (蘇州信諾維醫藥科技股份有限公司), now known as Evopoint Bioscience Co., Ltd.\* (蘇州信諾維醫藥科技股份有限公司), together with the Company as licensor, and Everest Medicines II (HK) Limited, as licensee, to out-license the right to develop and commercialize SN1011 globally for the treatment of renal diseases.

Pursuant to the License Agreement, the Company has received in 2021 US\$4 million upfront payment, and is entitled to up to an aggregate of US\$183 million in total development and sales milestones. The Company retains all other immunological rights for all indications (other than immunological related renal diseases) relating to SN1011 and will continue its research and development, including phase II clinical study currently initiating in China.

## **Production**

We carried out our manufacturing activities at our Haikou production base, where we manufacture our drug candidates for pre-clinical research, clinical trials and future large-scale production. The Haikou production base has a production capacity of 1,200 litres which is sufficient for clinical and initial marketing needs. The plant has an operational area consisting of a clean area for processing, a controlled-not-classified (CNC) area for supporting activities, utility rooms, quality control laboratories, warehouse and administrative offices. During the Reporting Period, the Haikou production base has expanded its total operational area from approximately 4,526 square metres to approximately 19,163 square metres.

Construction of the administrative facilities, testing laboratories and R&D laboratories of our Suzhou base in China was completed in 2019. The administrative facilities have been in operation since late-2020 for supporting ongoing and new product development projects. To cope with the Company's business development plan in expanding R&D and product development capacity, a new research laboratory will be established in the Company's new Suzhou campus and the production capability of our Suzhou base as reported in our 2020 Annual Report will also be taken up by the new Suzhou campus. During the Reporting Period, the R&D laboratories of our Suzhou base have been fully equipped and have come into full operation since December 2021.

As previously reported, the Company, on 24 June 2020, purchased a piece of land of 43,158 square metres in Suzhou Dushu Lake High Education Town, China, where the Company plans to build its PRC headquarters, an R&D centre as well as another production base of the Group, with a total floor area of approximately 75,000 square metres. This new Suzhou campus consists of a manufacturing shop, a pilot plant, an R&D centre, a quality inspection centre, a clinical study centre and an administration building. The superstructure works have been completed in December 2021 and the interior fitting-out works are planned to commence in the first half of 2022. The development of the new Suzhou campus will be completed and come into operation in phases. Phase I development with a production capacity of 6,000 litres is expected to come into operation in early 2023. Upon completion of the new Suzhou campus, the production capacity of the production base would be over 32,000 litres.

## **Intellectual property**

### ***Core technology of main drugs (products)***

For SM03 (Suciraslimab), the Company has two invention patents which are granted and registered in the PRC, of which one invention patent is also applicable to SM06, and four invention patents which are granted and registered in the United States, all of which are also applicable to SM06.

For SN1011, the Company has one invention patent registered in the United States which was granted during the Reporting Period.

For SM09, the Company has two invention patents granted and registered in the PRC. The Company also holds three invention patents granted and registered in the United States for SM09.

During the Reporting Period, the Company has filed two invention patent applications for Suciraslimab which are also applicable to SM06 in the United States. The two previously filed Patent Cooperation Treaty (PCT) patent applications, both of which are also applicable to SM06, have entered national phase in the United States, Europe, and the PRC, respectively in 2021. As at 31 December 2021, the Company has four pending patent applications in the United States, two pending patent applications in the PRC, and two pending patent applications in the Europe.

### ***Well-known or famous trademarks***

The Company conducts its business under the brand name of “SinoMab” (“中國抗體”). As at the end of the Reporting Period, the Company had various registered trademarks in Hong Kong and the PRC and trademark applications pending approval in the PRC.

### ***Patents***

<b>Item</b>	<b>As at 31 December 2021</b>	<b>As at 31 December 2020</b>
Number of invention patents owned by the Company*	<b>25</b>	19

\* *including patent pending and granted patent.*

### **R&D personnel**

<b>Education level</b>	<b>Number at the end of the Reporting Period</b>	<b>Number at the beginning of the Reporting Period</b>
PhD	<b>8</b>	7
Master	<b>17</b>	11
Undergraduate or below	<b>13</b>	7
Total number of R&D personnel	<b>38</b>	25

The above number of R&D personnel does not include our employees in manufacturing, quality assurance or quality control for the clinically related operation.

### **Major government R&D grants, funding, subsidies and tax preference**

During the Reporting Period, the Company received a total of 5 government grants.

## **Future and prospects**

We strive to become a leading global biopharmaceutical company for the development of novel drugs to fulfil unmet medical needs through our Hong Kong-based R&D and innovation, and PRC-based manufacturing capabilities. Our vision is to become a global leader in the innovation of therapeutics for immunological and other debilitating diseases.

Our portfolio of drug candidates encompasses the entire immunological field which, we believe, will enable us to provide comprehensive treatment options for field-wide indications to patients. We believe our dedication, experience and achievements in the field of immunology have expedited the process, and elevated the industry standard, for the discovery and development of novel therapeutics against a variety of immunological diseases. As a result, we have accumulated significant experience in the discovery of new treatment modalities for immunological diseases, which will allow us to better capture a substantial share of the immunological disease market. We believe that our strategic specialisation and dedicated focus on immunological diseases is an effective way to differentiate ourselves from our peers. By specialising in innovative treatments of immunological diseases, we seek to solidify our leading position in the field, thereby creating a higher barrier to entry for our peers to compete with us in the development of first-in-target or first-in-class drug candidates.

Further, our product pipeline is backed by our established full-spectrum platform integrating in-house capabilities across the industry chain, for instance, our strong and independent target identification, drug candidate development, pre-clinical research, clinical trials, clinical production, quality control, quality assurance, regulatory approval and commercial-scale production up to the commercialisation stage, as well as all other processes in the discovery and development of our drug candidates. We believe that this full-fledged capability is matched by only a few biopharmaceutical companies in the Greater China region.

With a diverse and expanding product pipeline, we believe that we are well positioned to become an industry leader in the development of treatments for immunological diseases.

The Group will continue to focus on the advancement of our flagship product SM03 (Suciraslimab) towards commercialisation, further progress our existing product pipeline, discover and develop novel drugs for the treatment of immunological diseases by leveraging our R&D capabilities, expand our production scale to support our product commercialisation and strengthen our global presence through leveraging our position as a Hong Kong-based biopharmaceutical company.

The Company is committed to educating its current and potential investors in respect of the Company's products and pipeline development, for example, through non-deal roadshows.



### ***Clinical development plan***

We will continue to advance clinical trials for SM03 (Suciraslimab) for RA and other autoimmune diseases. As previously mentioned, we expect to file our Suciraslimab NDA for RA with the NMPA in the coming years. In terms of the broader indication development, we will advance clinical trials for SLE, SS and other autoimmune diseases. We expect to initiate phase II clinical study for SLE in China in the second half of 2022. We are also in the process of further broadening therapeutic area of SM03 (Suciraslimab), seeking regulatory pathways to extrapolate the clinical indications of neuro-immunological diseases for SM03.

We will continue the global clinical development programme for SN1011 in the immunological disease area. Based on INDs obtained from NMPA for the treatment of SLE and Pemphigus, and the completed phase I trials for healthy subjects in China, the Company is initiating Phase II clinical study targeting Pemphigus in China. The Company is also preparing global trial in MS and is expected to obtain IND in both China and the US in 2022. The Company also plans to apply for other INDs and/or proof-of-concept clinical studies for SN1011 in the near future.

In respect of SM17, we plan to enter into human clinical trials in the U.S. by the first quarter of 2022 and the earliest time for phase I results will be in the first half of 2023. Proof-of-concept studies will then be conducted to evaluate the primary efficacy of SM17 in Asthma or other indications, if supported by good tolerability and safety results from phase I, which is expected.

As for SM06, we will advance the first IND application process, aiming for a bio-better product development for known indications based on good therapeutic potential of SM03 or further exploration for other immunological diseases with unmet medical needs.

### ***Pre-clinical R&D***

We are in the process of building a pre-clinical R&D platform for studying pathogenesis of autoimmune diseases, as well as exploring and identifying solid treatment for them. Our internal R&D team is in the process of discovering novel mechanisms for treatment of multiple autoimmune diseases areas for rheumatology, neuro-immunology, respiratory and dermatology. Our R&D team possesses the capability of generating pre-clinical pharmacology internally and are developing in-depth collaboration with well-known clinical KOLs from our on-going clinical programs. By utilizing established business and cooperation relationship with vendors/patterners, the Company is in the process of generating and collecting the IND-enabling data package for our multiple products under pre-clinical development, such as SM17 and SM06, and will thereafter conduct pre-clinical studies to test their efficacies, safety and PK/PD, and fulfil other regulatory requirements.

The Company continues to optimize production and preclinical research for SM09 and TNF2. It is expected that these pre-clinical researches will complete in one year, after which the Company will engage NMPA and/or FDA to initiate clinical trials.

### ***Novel drug targets identification***

The Company has been actively exploring novel targets identification. The Company has engaged D2M Biotherapeutics Limited (“**D2M**”) for a long-term collaboration for the identification of novel drug targets, for which the Company is entitled to conduct subsequent researches, development and commercialization with regards to qualified drug targets which are chosen by the Company from the original results of D2M’s target identification works according to a prioritized target-selection mechanism.

### ***Production***

As previously reported, on 24 June 2020, the Company purchased a piece of land of 43,158 square metres in Suzhou Dushu Lake High Education Town, China, where the Company plans to build its PRC headquarters, an R&D centre as well as another production base, with a total floor area of approximately 75,000 square metres. This new Suzhou campus consists of a manufacturing shop, a pilot plant, an R&D centre, a quality inspection centre, a clinical study centre and an administration building. The superstructure works have been completed in December 2021 and the interior fitting-out works are expected to commence in the first half of 2022. The development of the new Suzhou campus will be completed and come into operation in phases. Phase I development with a production capacity of 6,000 litres is expected to come into operation in early 2023. Upon completion of the new Suzhou campus, the production capacity of the production base would be over 32,000 litres.

### ***Commercialisation***

Albeit uncertainties associated with COVID-19, we expect to build up our sales team by 2022. The leader of sales and marketing was on board in February 2022. Our commercialisation team is expected to cover a majority of provinces and municipalities in China and to support the future commercialisation of our drug candidates. We are actively exploring and identifying opportunities for collaboration and/or partnership, including but not limited to licensing in or licensing out, to enhance our sales and business development capabilities.

## ***COVID-19***

Where the outbreak of COVID-19 continues and/or worsens, the Company's clinical trial development will continue to be affected. As of the date of this announcement, the pandemic has affected one clinical trial in the PRC since a number of out-patient clinics have closed temporarily, patients or subjects have generally avoided visiting hospitals and certain hospitals have put on hold the enrollment of patients or subjects for clinical trials. Save as disclosed in this announcement, as at the date of this announcement, all other operations of the Company have been conducted as normal so far, but can be impacted if the pandemic continues.

## **RISK FACTORS**

### **R&D risk of new drugs**

Classified as technical innovations, the R&D of new drugs is characterised by long R&D cycles, significant investment, high risks and a low success rate. From laboratory research to obtaining approval, new drugs have to go through a lengthy process linked by complicated stages, including pre-clinical studies, clinical trials, registration and marketing of new drugs and after-sales supervision. Any of the above stages is subject to the risk of failure.

The Company will strengthen its forward-looking strategic research, and determine the direction of new drug R&D according to the needs of clinical drug use. The Company will also formulate reasonable new drug technology solutions, continuously increase the investment in R&D of new drugs, and uphold the principle of prudence in launching R&D projects for new drugs. In particular, the Company implements phase-based assessments on product candidates in the course of R&D. If it is found that the expected result cannot be achieved, the subsequent R&D of such product candidates will be terminated at once, so as to minimise the R&D risk of new drugs.

### **Market competition risk**

The R&D and commercialisation of new drugs is highly competitive. The Company's recent drug candidates and any new drugs that may be sought for R&D and commercialisation in the future will face competition from pharmaceutical companies and biotechnology companies around the world. The Company's commercial opportunity could be reduced or eliminated if our competitors develop and commercialise drugs that are safer, are more effective or have fewer side effects than the drugs we have developed. The Company's competitors may also obtain approval from the NMPA or FDA sooner than the Company obtaining approval for its drugs, such that the competitors may establish a strong market position before the Company is able to enter the market. The Company will maintain its market competitiveness with its rapid advancement in R&D and clinical trials of drugs, corroborant efficacy and stable production process.

### **Quality control risk of drugs**

The quality and safety of drugs not only concern the health of drug users but also arouse wide public concern. Due to various factors, drugs are subject to quality control risks in all stages, including R&D, manufacturing, distribution and use. Therefore, risk control runs through the entire process of drug development, manufacturing, distribution, and use. The Company will secure necessary resources, strengthen training in risk management, and improve various rules and regulations, so as to ensure strict compliance with the GMP standards and control the quality risk of drugs.

### **Risk of not making profit in short run**

One of the most prominent characteristics of the biopharmaceutical industry is a long profit cycle. Generally, a biopharmaceutical enterprise at the R&D stage takes a longer time to reach profitability. As an early-stage biopharmaceutical enterprise, the Company is under a period of making significant R&D investment. With the further supplement of product pipelines, as well as rapid advancement in domestic and international clinical trials for drug candidates, the Company will continue to make significant R&D investment. Our future profit will depend on the marketing progress of drug candidates and the sale of marketed drugs. In addition, significant R&D investment, business promotion costs and operation costs create more uncertainties over making profits. Therefore, the Company is subject to the risk of not making a profit in the short run.

### **Risk of industry regulations and policies**

In view of the various reforms in the medical industry, encouragement of innovation and reduction in drug prices by pharmaceutical enterprises have become an inevitable trend. The Company will adapt to changes in external policies and strive to enhance R&D, in order to respond to challenges through innovation. The Company will also adhere to legal compliance by adapting its business activities to changes in regulatory policies, thereby preventing policy risks.

In the face of industry and policy risks, the Company will adapt to changes in external policies by continuous improvement in capabilities of innovation and sustainable development, increased R&D investment, accelerated clinical trials and launching of innovative drugs, in order to respond to challenges through innovation. On this basis, the Company will further expand its production capacity and reduce the unit cost of its products, so as to address the trend of price reduction of drugs.

### **Foreign exchange risk**

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which the Group conducts business may affect the Group's financial condition and results of operations.

In response to the foreign exchange risk, the Company seeks to limit its exposure to foreign currency risk by minimising its net foreign currency position to reduce the impact of the foreign exchange risk on the Company.

## FINANCIAL REVIEW

### Other income and gains

Our other income and gains consist primarily of bank interest income, changes in fair value on a financial asset at fair value through profit or loss, government grants and foreign exchange gain. Total other income and gains were approximately RMB28.8 million for the Reporting Period, representing a decrease of approximately RMB29.7 million from the year ended 31 December 2020, mainly due to (i) a decrease in fair value gain on financial assets at fair value through profit or loss amounting to approximately RMB26.9 million; (ii) a decrease in government grants amounting to approximately RMB12.0 million and offset by (iii) an increase in foreign exchange gain, net of approximately RMB9.9 million.

### R&D costs

	Year ended 31 December	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Laboratory consumable and experiment costs	<b>151,707</b>	79,891
Employment costs	<b>35,427</b>	17,228
Others	<b>11,979</b>	6,283
	<b>199,113</b>	103,402

Our R&D costs mainly include laboratory consumables, experiment costs, employment costs of R&D employees, depreciation of right-of-use assets relating to leases of research facilities and depreciation of research and testing equipment.

For the years ended 31 December 2021 and 2020, we incurred R&D costs of approximately RMB199.1 million and RMB103.4 million, respectively. The increase in our costs of business development in R&D during the Reporting Period, was mainly attributable to (i) an increase in the laboratory consumable and experiment costs of approximately RMB71.8 million for our R&D or clinical projects; and (ii) an increase in the employment costs of approximately RMB18.2 million for the expansion of our clinical department.

## **Administrative expenses**

Our administrative expenses primarily consist of employee costs of administrative personnel, depreciation of right-of-use assets relating to leases of office space, depreciation and amortisation, rental and property management fees, consulting and auditing expenses, legal and other professional advisory service fees, office expenses, transportation costs and others.

For the years ended 31 December 2021 and 2020, our total administrative expenses were approximately RMB133.4 million and RMB72.0 million, respectively. The increase was mainly due to (i) the increase in the recognition of a non-cash share-based payment (being the grant of restricted share units (“**RSUs**”) under the RSU scheme of approximately RMB28.0 million); (ii) an increase in the employment related costs for our business expansion of approximately RMB11.4 million; and (iii) an increase in the depreciation of property, plant and equipment, right-of-use assets and amortisation of intangible assets of approximately RMB7.5 million.

## **Liquidity and capital resources**

The Group has always adopted a prudent treasury management policy. The Group places strong emphasis on having funds readily available and accessible and is in a stable liquidity position with sufficient funds in standby banking facilities to cope with daily operations and meet its future development demands for capital.

As at 31 December 2021, our bank balance and cash totalled RMB563.0 million, as compared to RMB810.4 million as at 31 December 2020. The decrease was mainly due to (i) the capital expenditures of subsidiaries in Suzhou and Hainan, of approximately RMB211.3 million; (ii) the purchase of shares under the share award scheme of approximately RMB59.7 million; (iii) an investment in D2M Biotherapeutics Limited, of approximately RMB16.2 million; (iv) the expenses paid for operating activities, of approximately RMB147.1 million; and offset by (v) the increase in the net bank borrowing of approximately RMB138.3 million; and (vi) the sales proceeds received from the disposed of the investment in the China Healthcare Fund which is a segregated portfolio of New China Overseas Opportunity Fund SPC of approximately RMB92.0 million.

The following table sets forth a condensed summary of the Group's consolidated statement of cash flows for the years ended indicated and analysis of balances of cash and cash equivalents for the years ended indicated:

	<b>31 December 2021 RMB'000</b>	31 December 2020 RMB'000
Net cash flows used in operating activities	(147,063)	(141,338)
Net cash flows used in investing activities	(137,702)	(179,218)
Net cash flows from/(used in) financing activities	57,515	(18,808)
Net decrease in cash and cash equivalents	(227,250)	(339,364)
Cash and cash equivalents at the beginning of the year	810,370	1,200,868
Effect of foreign exchange rate changes, net	(20,137)	(51,134)
Cash and cash equivalents at the end of the year	<u>562,983</u>	<u>810,370</u>
Analysis of balances of cash and cash equivalents		
Cash and bank balances	399,983	77,606
Non-pledged time deposits with original maturity of less than three months when acquired	<u>163,000</u>	<u>732,764</u>
Cash and cash equivalents as stated in the statement of cash flows	<u>562,983</u>	<u>810,370</u>

As at 31 December 2021, cash and cash equivalents were mainly denominated in Renminbi, United States dollars and Hong Kong dollars.

### **Bank borrowing and gearing ratio**

As at 31 December 2021, the Group's outstanding borrowing of RMB198.8 million (31 December 2020: RMB60.5 million) were denominated in RMB and carried at a variable rate of interest ranging from the People's Bank of China RMB Loan Prime Rate minus 0.30% to the People's Bank of China RMB Loan Prime Rate plus 0.25%.

The Group monitored capital using gearing ratio. Gearing ratio is calculated using interest-bearing bank borrowing less cash and cash equivalents divided by total equity and multiplied by 100%. During the Reporting Period, the Group always maintained a net cash position.

### **Pledge of Asset**

As at 31 December 2021, land use right of net carrying amount of approximately RMB15.5 million was pledged to secure the bank loan borrowed by the Group (2020: Nil).



## **Significant investment held and disposed**

During the Reporting Period, the Company completed its disposal of 775,347.912 units of Class A participating shares (the “**Investment**”) in the China Healthcare Fund, which is a segregated portfolio of New China Overseas Opportunity Fund SPC (“**New China Overseas**”). The Investment was made by the Company on 22 January 2020 at a cost of HK\$78 million. On 4 February 2021, the Company (as seller) and Dragon Capital Special Opportunities SPC for and on behalf of its segregated portfolio named Dragon Capital Special Opportunities 2 SP (as purchaser) entered into a contract to sell the Investment at a consideration of approximately HK\$110.6 million (the “**Disposal**”) which represented approximately 8.24% of the total assets of the Company for the financial year ended 31 December 2020. The Disposal was completed on 18 February 2021 and the Company recognised unrealised gain from change in fair value of the Investment of approximately RMB28.3 million (approximately HK\$32.6 million, representing approximately 41.76% return on Investment) for the financial year ended 31 December 2020.

New China Overseas is an open-ended investment company incorporated in the Cayman Islands with limited liability on 17 October 2014 and registered as an exempted segregated portfolio company with the Registrar of Companies of the Cayman Islands.

The Investment served as a corporate investment strategy to maintain and generate possible future income of the Company and was a means to better utilise the Company’s current financial resources, and fell under “other general corporate purposes” of the Company’s planned use of proceeds from the Company’s listing. The Investment matured on 22 January 2021 and could be redeemed since then.

Please refer to the Company’s announcements dated 4 February 2021 and 5 February 2021, and the paragraph headed “SIGNIFICANT INVESTMENTS HELD” under “Management Discussion and Analysis” section of the Company’s 2020 Annual Report for more details. Save as disclosed, the Company did not hold and dispose of any significant investment with a value greater than 5% of the Company’s total assets as at 31 December 2021.

## **Material Event — Possible issue of Convertible Bonds under Subscription Agreement (Lapsed)**

As reported in the Company’s 2020 Annual Report, a subscription agreement (the “**Subscription Agreement**”) was entered into on 22 December 2020 between the Company (the issuer) and Haiyao international Group Limited (the “**Investor**”) in respect of the subscription by the Investor for convertible bonds in an aggregate principal amount of HK\$100,000,000 (“**Convertible Bonds**”). The Subscription Agreement has lapsed on 22 June 2021.

Details of the Subscription Agreement and the proposed issue of the Convertible Bonds, and the lapse of the proposed issue of Convertible Bonds were disclosed in the announcement of the Company dated 22 December 2020, 14 January 2021 and 22 June 2021 and the circular of the Company dated 27 January 2021.

### **Global offering and use of proceeds**

On 12 November 2019, the Company's shares were listed on The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") and the Company raised net proceeds of HK\$1,272.80 million ("**Net Proceeds**") and the unutilised balance of Net Proceeds as at 31 December 2021 was approximately HK\$522.5 million. In respect of the use of proceeds in the prospectus dated 31 October 2019 (the "**Prospectus**") and subsequent change in use of proceeds announcement issued by the Company dated 22 July 2020 (the "**Announcement**"), the Board has resolved to change the use of the unutilised Net Proceeds.

### **Change in use of proceeds**

To better use the unutilised Net Proceeds, the Company decides to reallocate HK\$50 million from the use of net proceeds from "For the purchase of land from the Suzhou Dushu Lake Higher Education Town and other expenses related to the expansion of our Suzhou production base" to (i) HK\$10.0 million to "*For our working capital, expanding internal capabilities and other general corporate purposes*"; (ii) HK\$30.0 million to "*For the R&D and commercialization of our core product, SM03, to fund clinical trials for SM03*"; and (iii) HK\$10 million to "*To further advance our R&D programs, expand our R&D team, build our commercialization team, develop our proprietary technology and enhance our full-spectrum platform*".

Cost saving measure and budgetary control have been strictly in place on the construction project of our Suzhou production base since the land is purchased and the commencement of construction. The project has been in good progress and in good control of financing. The superstructure works have been completed and a topping up ceremony was held in December 2021. In view of the plentiful planned resources to the Suzhou project, the Board considered that HK\$50 million out of the original planned applications could be reallocated to other segments.

In considering the current balance of unutilised net proceeds for the R&D and commercialization of our core product, SM03, the Board considered that it would be appropriate to relocate HK\$30 million for SM03 for its commercialization in 2023.

During the Reporting Period, the Company has added a number of new indications into its pipeline and successfully expanded its pipeline. The Board recognized the importance of expanding the pipeline and considered it would be appropriate to reallocate HK\$10 million to further advance our R&D programs, expand our R&D team, develop our proprietary technology and enhance our full-spectrum platform.

Considering the rapid expansion of our Group, the Board also considered that it would be appropriate to reallocate HK\$10 million for the use of our working capital, expanding internal capabilities and other general corporate purposes.

The Board considered the impact of the proposed change in the use of the proceeds on the Group's business and believes that, in view of the Group's operation and business development, the reallocation of the unutilised Net Proceeds will facilitate efficient allocation of financial resources and strengthen the future development of the Group, and it is appropriate and in the interests of the Company and its shareholders as a whole. Save for the above, there is no other change in the use of Net Proceeds.

Use of proceeds	Planned applications <sup>(Note 1)</sup> (HK\$ million)	Revised allocation (HK\$ million)	Actual utilisation up to 31 December 2021 (HK\$ million)	Unutilised net proceeds as at 31 December 2021 (HK\$ million)	Expected timeline for full utilisation of the unutilised net proceeds <sup>(Note 2)</sup>
<i>For the R&amp;D and commercialization of our drug candidates</i>					
For the R&D and commercialization of our core product, SM03, to fund clinical trials for SM03 including (i) ongoing and planned clinical trials in the PRC; (ii) additional clinical trials to be initiated in the PRC for additional indications; (iii) clinical trials in Australia and the United States; and (iv) New Drug Application registration filings and the commercial launch of SM03	190.9	220.9	190.0	30.9	By the end of 2022
To fund pre-clinical research, clinical trials, production, preparation for registration filings and potential commercial launches of the other drug candidates in our pipeline	279.4	279.4	200.6	78.8	By the end of 2023
To further advance our R&D programmes, expand our R&D team, build our commercialization team, develop our proprietary technology and enhance our full-spectrum platform	42.4	52.4	42.4	10.0	By the end of 2022
For the discovery and development of new drug candidates not currently in our pipeline to diversify our product portfolio	84.9	84.9	55.7	29.2	N/A <sup>(Note 3)</sup>
<i>For the construction of our Suzhou production base primarily for the commercial-scale production of our core product SM03</i>					
For the purchase of laboratory equipment, primarily for the R&D of SM03 and potentially for the R&D of other products in our pipeline	85.8	85.8	19.4	66.4	By the end of 2022
For the purchase of manufacturing equipment, primarily for the production of SM03	59.7	59.7	–	59.7	By the end of 2022
<i>For the construction of the Suzhou production base</i>					
For the construction of additional R&D facilities and purchase of laboratory equipment to aid the ongoing R&D of SM03 for the treatment of rheumatoid arthritis, systemic lupus erythematosus, non-Hodgkin's lymphoma and other potential indications, R&D of SM03 at commercialization to enhance craftsmanship for large-scale production, as well as the development of other products in our pipeline	107.6	107.6	31.2	76.4	By the end of 2022

Use of proceeds	Planned applications <sup>(Note 1)</sup> (HK\$ million)	Revised allocation (HK\$ million)	Actual utilisation up to 31 December 2021 (HK\$ million)	Unutilised net proceeds as at 31 December 2021 (HK\$ million)	Expected timeline for full utilisation of the unutilised net proceeds <sup>(Note 2)</sup>
For the construction of an upstream production facility and downstream purification facility	88.2	88.2	–	88.2	By the end of 2022
For the purchase of land from the Suzhou Dushu Lake Higher Education Town and other expenses related to the expansion of our Suzhou production base	167.9	117.9	70.6	47.3	By the end of 2023
For our working capital, expanding internal capabilities and other general corporate purposes	127.2	137.2	101.6	35.6 <sup>(Note 4)</sup>	N/A
Collaboration with D2M Group	38.8	38.8	38.8	–	N/A
Total	<u>1,272.8</u>	<u>1,272.8</u>	<u>750.3</u>	<u>522.5</u>	

*Notes:*

- (1) Planned applications as revised and disclosed in the Company's announcements dated 22 July 2020 and 14 August 2020.
- (2) The expected timeline for utilising the unutilised net proceeds is based on the best estimation made by the Group. It is subject to change based on the future development and events which may be outside of the Group's control.
- (3) As the discovery and development of new drug candidates not currently in pipeline is a continuous and ongoing process, the Company is unable to set out a detailed timeline for the utilisation of such net proceeds.
- (4) Costs of HK\$78.0 million for the Investment in China Healthcare Fund were returned to this planned application. As disclosed in the Company's announcement dated 4 February 2021 and the 2020 Annual Report, the Investment was disposed of at a consideration of approximately HK\$110.6 million. Please refer to the preceding paragraph headed "Significant investment held and disposed" in this section to this announcement for more details.

Save as the changes disclosed above, such utilisation of the net proceeds was in accordance with the planned applications as set out in the above. The unutilised portion of the net proceeds will be applied in a manner consistent with the above planned applications.

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

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

## **MODEL CODE FOR DIRECTORS' SECURITIES TRANSACTIONS**

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules as its own code of conduct regarding Directors' securities transactions. Having made specific enquiries with each of the Directors, all the Directors confirmed that they had complied with such code of conduct throughout the year ended 31 December 2021.

## **PRELIMINARY ANNOUNCEMENT OF AUDITED ANNUAL RESULTS**

The financial information relating to the years ended 31 December 2021 and 2020 included in this announcement does not constitute the Company's statutory annual consolidated financial statements for both years but is derived from those financial statements. Further information relating to these statutory financial statements required to be disclosed in accordance with section 436 of the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) (the "**Companies Ordinance**") is as follows:

- The Company has delivered the financial statements for the year ended 31 December 2020 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Companies Ordinance and will deliver the financial statements for the year ended 31 December 2021 to the Registrar of Companies in due course.
- The Company's auditor has reported on the financial statements of the Group for both years. The auditor's reports were unqualified, did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its reports, and did not contain a statement under sections 406(2), 407(2) or 407(3) of the Companies Ordinance.

## **EVENTS AFTER REPORTING PERIOD**

There are no significant events that affected the Group after the Reporting Period and up to the date of this announcement.

## **CORPORATE GOVERNANCE**

The Board is committed to achieving high corporate governance standards. The Board believes that high corporate governance standards are essential to providing a framework for the Group to safeguard the interests of shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability. The Company has applied the principles and code provisions as set out in the Corporate Governance Code (the "**CG Code**") contained in Appendix 14 to the Listing Rules throughout the Reporting Period.

The Board is of the view that throughout the Reporting Period, the Company has complied with all code provisions as set out in the CG Code, save for the deviation as disclosed below.

Pursuant to code provision A.2.1 in the CG Code, the roles of the chairman and chief executive should be separate and should not be performed by the same individual. Dr. Shui On LEUNG (“**Dr. Leung**”) is currently both the chairman and the chief executive officer of the Company. The Board believes that Dr. Leung is the Director best suited, among all Directors, to identify strategic opportunities and focus in view of his extensive understanding of the Company’s business as a founder and the chief executive officer. The Board further believes that the combined role of chairman and chief executive officer will not impair the balance of power and authority between the Board and the management of our Company, given that: (i) decisions to be made by the Board require approval by at least a majority of the Directors; (ii) Dr. Leung and the other Directors are aware of and have undertaken to fulfil their fiduciary duties as Directors, which require, amongst other things, that they act for the benefit and in the best interests of the Company as a whole and will make decisions for the Company accordingly; (iii) the balance of power and authority is protected by the operations of the Board, which consists of an executive Director (Dr. Leung), six non-executive Directors and four independent non-executive Directors, and has a fairly strong independence element; and (iv) the overall strategies and other key business, financial, and operational policies of the Company are made collectively after thorough discussions at both the Board and senior management levels. Therefore, the Board considers that it is in the best interest of the Group for Dr. Leung to take up both roles for business development and effective management, and the deviation from the code provision A.2.1 in the CG Code is appropriate in such circumstances.

## **AUDIT COMMITTEE**

The Audit Committee comprises four independent non-executive Directors, being Mr. Ping Cho Terence HON (Chairman), Mr. George William Hunter CAUTHERLEY, Dr. Chi Ming LEE and Mr. Dylan Carlo TINKER. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, risk management and internal control and systems of the Group and overseeing the audit process and the relationship between the Company and its auditor.

The Audit Committee has reviewed alongside the management and external auditor the accounting principles and policies adopted by the Group and the audited consolidated financial statements for the Reporting Period.

## **SCOPE OF WORK OF THE GROUP'S AUDITOR**

The figures in respect of the Group's consolidated statement of financial position, consolidated statements of profit or loss, consolidated statement of comprehensive income and the related notes thereto for the year ended 31 December 2021 as set out in this annual results announcement have been agreed by the Group's auditor, Ernst & Young, to the amounts set out in the Group's audited consolidated financial statements for the year ended 31 December 2021 prepared in accordance with HKFRSs. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on this annual results announcement.

## **ANNUAL GENERAL MEETING**

The annual general meeting of the Company (the "AGM") will be held on Monday, 13 June 2022. The notice of the AGM will be published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.sinomab.com](http://www.sinomab.com)) and despatched to the shareholders of the Company in the manner as required by the Listing Rules in due course.

## **FINAL DIVIDEND**

The Board does not recommend payment of a final dividend for the Reporting Period.

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

The register of members of the Company will be closed from Wednesday, 8 June 2022 to Monday, 13 June 2022, both days inclusive, during which no transfer of shares will be registered, in order to determine the holders of the shares of the Company who are entitled to attend and vote at the AGM. In order to be eligible to attend and vote at the AGM, all transfers of the shares accompanied by the relevant share certificates and transfer forms must be lodged with the Company's share registrar in Hong Kong, 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 Tuesday, 7 June 2022 (Hong Kong time, being the last share registration date).



**CONSOLIDATED STATEMENT OF PROFIT OR LOSS**  
**YEAR ENDED 31 DECEMBER 2021**

	<i>Notes</i>	<b>2021</b> <b>RMB'000</b>	2020 <i>RMB'000</i>
REVENUE	3	<b>25,913</b>	–
Other income and gains, net	3	<b>28,751</b>	58,439
Research and development costs		<b>(199,113)</b>	(103,402)
Administrative expenses		<b>(133,400)</b>	(72,010)
Finance costs		<b>(5,821)</b>	(2,416)
Other expenses		<b>(235)</b>	(2,464)
Share of loss of an associate		<b>(4,289)</b>	(747)
		<hr/>	<hr/>
LOSS BEFORE TAX		<b>(288,194)</b>	(122,600)
Income tax expenses	4	<b>–</b>	–
		<hr/>	<hr/>
LOSS FOR THE YEAR		<b>(288,194)</b>	(122,600)
		<hr/> <hr/>	<hr/> <hr/>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	5	<b>0.29</b>	0.12
		<hr/> <hr/>	<hr/> <hr/>

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**  
*YEAR ENDED 31 DECEMBER 2021*

	<b>2021</b>	2020
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
LOSS FOR THE YEAR	<u><b>(288,194)</b></u>	<u>(122,600)</u>
<b>OTHER COMPREHENSIVE LOSS</b>		
Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation to the presentation currency	<u>(20,710)</u>	<u>(57,687)</u>
<b>TOTAL COMPREHENSIVE LOSS FOR THE YEAR</b>	<u><b>(308,904)</b></u>	<u>(180,287)</u>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 DECEMBER 2021

	<i>Notes</i>	2021 <b>RMB'000</b>	2020 <b>RMB'000</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		253,285	101,093
Right-of-use assets		102,922	44,830
Investment in an associate		26,933	31,897
Intangible assets		1,921	–
Deposits		2,444	1,391
Other non-current assets	7	58,465	15,958
Total non-current assets		445,970	195,169
<b>CURRENT ASSETS</b>			
Prepayments, deposits and other receivables		32,702	30,926
Financial asset at fair value through profit or loss	8	–	93,058
Cash and cash equivalents		562,983	810,370
Total current assets		595,685	934,354
<b>CURRENT LIABILITIES</b>			
Other payables and accruals	9	85,970	44,674
Lease liabilities		7,394	9,130
Interest-bearing bank borrowing	10	5,000	5,000
Total current liabilities		98,364	58,804
NET CURRENT ASSETS		497,321	875,550
TOTAL ASSETS LESS CURRENT LIABILITIES		943,291	1,070,719
<b>NON-CURRENT LIABILITIES</b>			
Lease liabilities		69,288	28,247
Interest-bearing bank borrowings	10	193,777	55,461
Total non-current liabilities		263,065	83,708
Net assets		680,226	987,011
<b>EQUITY</b>			
Equity attributable to owners of the parent			
Share capital	11	1,679,126	1,679,126
Reserves		(998,900)	(692,115)
Total equity		680,226	987,011

## NOTES

### 1. GENERAL

The Company was established in Hong Kong on 27 April 2001 with limited liability. On 12 November 2019, the shares were listed on the Main Board of the Stock Exchange. The registered address of the Company is Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong. The principal activities of the Group are mainly research and development of pharmaceutical products.

The financial statements have been prepared under the historical cost convention, except for financial asset at fair value through profit or loss, which has been measured at fair value. These financial statements are presented in Renminbi ("RMB") and all values are rounded to the nearest thousand except where otherwise indicated.

### 2.1 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised HKFRSs for the first time for the current year's financial statements.

Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16	<i>Interest Rate Benchmark Reform – Phase 2</i>
Amendment to HKFRS 16	<i>Covid-19-Related Rent Concessions beyond 30 June 2021 (early adopted)</i>

The above amendments are not expected to have any significant impact on the Group's consolidated financial statements.

### 2.2 ISSUED BUT NOT YET EFFECTIVE HKFRSs

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

Amendments to HKFRS 3	<i>Reference to the Conceptual Framework<sup>1</sup></i>
Amendments to HKFRS 10 and HKAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture<sup>3</sup></i>
HKFRS 17	<i>Insurance Contracts<sup>2</sup></i>
Amendments to HKFRS 17	<i>Insurance Contract<sup>2,5</sup></i>
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-current<sup>2,4</sup></i>
Amendments to HKAS 1 and HKFRS Practice Statement 2	<i>Disclosure of Accounting Policies<sup>2</sup></i>
Amendments to HKAS 8	<i>Definition of Accounting Estimates<sup>2</sup></i>
Amendments to HKAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction<sup>2</sup></i>
Amendments to HKAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use<sup>1</sup></i>
Amendments to HKAS 37	<i>Onerous Contracts — Cost of Fulfilling a Contract<sup>1</sup></i>
<i>Annual Improvements to HKFRSs 2018-2020</i>	<i>Amendments to HKFRS 1, HKFRS 9, Illustrative Examples accompanying HKFRS 16, and HKAS 41<sup>1</sup></i>

<sup>1</sup> Effective for annual periods beginning on or after 1 January 2022

<sup>2</sup> Effective for annual periods beginning on or after 1 January 2023

<sup>3</sup> No mandatory effective date yet determined but available for adoption

<sup>4</sup> As a consequence of the amendments to HKAS 1, Hong Kong Interpretation 5 *Presentation of Financial Statements — Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause* was revised in October 2020 to align the corresponding wording with no change in conclusion

<sup>5</sup> As a consequence of the amendments to HKFRS 17 issued in October 2020, HKFRS 4 was amended to extend the temporary exemption that permits insurers to apply HKAS 39 rather than HKFRS 9 for annual periods beginning before 1 January 2023

The directors of the Company anticipate that application of the new and revised HKFRSs and interpretations will have no material impact on the Group's consolidated financial statements in the future.

### 3. REVENUE, OTHER INCOME AND GAINS, NET

An analysis of revenue is as follows:

	<i>Note</i>	<b>2021</b> <b>RMB'000</b>	2020 RMB'000
Revenue from contract with a customer	(i)	<b>25,913</b>	—

Disaggregated revenue information

#### For the year ended 31 December 2021

	Licence revenue RMB'000
<b>Type of goods or services</b>	
Licence revenue	<u>25,913</u>
<b>Geographical market</b>	
Hong Kong	<u>25,913</u>
<b>Timing of revenue recognition</b>	
Licence revenue at a point in time	<u>25,913</u>

*Note:*

- (i) On 16 September 2021, the Company entered into an exclusive licensing agreement with Everest Medicines II (HK) Limited ("Everest") to out-license the right to develop and commercialise Bruton's tyrosine kinase inhibitor ("BTK"), to Everest globally for the treatment of renal diseases relating to SN1011. On 21 December 2021, the Company received the non-refundable upfront payment according to the above agreement, and this upfront payment was recognised in the statement of profit or loss during the year ended 31 December 2021.

An analysis of other income and gains, net is as follows:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
<b>Other income and gains, net</b>		
Bank interest income	16,731	17,346
Foreign exchange gain, net	9,877	–
Government grants	744	12,760
Fair value gain on financial instruments at fair value through profit or loss	1,344	28,253
Others	55	80
	<u>28,751</u>	<u>58,439</u>

The government grants mainly represent grants received from the local governments for the purpose of support for research activities and clinical trials and award for the successful listing of the Company. There were no unfulfilled conditions or contingences relating to these grants received during the year.

#### 4. INCOME TAX

No Hong Kong profit tax has been made as the Company did not generate any assessable profit during the year (2020: Nil).

Under the Law of the PRC of Enterprise Income tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the estimated tax rate of the Group’s PRC subsidiaries is 25% during the period presented in the consolidated financial statements. No PRC Enterprise Income tax was provided for as there was no estimated assessable profit of the Group’s PRC subsidiaries during the periods presented in the consolidated financial statements.

Taxes on profits assessable elsewhere have been calculated at the rates of tax prevailing in the countries (or jurisdictions) in which the Group operates.

Deferred taxation had not been recognised on the unused tax losses and deductible temporary differences due to the unpredictability of future profit streams.

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

The calculation of the basic loss per share is based on the consolidated loss for the year attributable to ordinary equity holders of the parent of RMB288,194,000 (2020: RMB122,600,000), and the weighted average number of ordinary shares of 994,887,333 (2020: 1,006,240,400) in issue during the year, as adjusted to exclude the shares held under the share award scheme of the Company.

No adjustment has been made to basic loss per share presented for the years ended 31 December 2021 and 2020 as the Group has no potentially dilutive ordinary shares in issue during those years.

The calculations of basic and diluted loss per share are based on:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
<b>Loss</b>		
Loss attributable to ordinary equity holders of the parent	<u>288,194</u>	<u>122,600</u>

	<b>Number of shares</b>	
	2021	2020
<b>Shares</b>		
Weighted average number of ordinary shares in issue during the year	<u>994,887,333</u>	<u>1,006,240,400</u>

## 6. DIVIDEND

No dividend was paid or declared by the Company during the years ended 31 December 2021 and 2020.

## 7. OTHER NON-CURRENT ASSETS

Deposits for purchases of property, plant and equipment relates to the construction of Suzhou production base primarily for the commercial-scale production of the core product SM03.

## 8. FINANCIAL ASSET AT FAIR VALUE THROUGH PROFIT OR LOSS

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Unlisted investment, at fair value	<u>–</u>	<u>93,058</u>

## 9. OTHER PAYABLES AND ACCRUALS

	<i>Notes</i>	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Other payables and accrued expenses	<i>(i)</i>	48,580	21,208
Costs of construction and purchase of equipment payables	<i>(ii)</i>	27,266	3,855
Payroll payable		7,457	1,578
Deferred revenue		1,550	1,554
Taxes other than corporate income tax		397	167
Amount due to a director	<i>(iii)</i>	720	–
Payable for an investment in an associate		<u>–</u>	<u>16,312</u>
		<u>85,970</u>	<u>44,674</u>

*Notes:*

- (i) Other payables and accrued expenses primarily consists of service fees payable to outsourced service providers including contract research organisations and clinical trial centres.



- (ii) Costs of construction and purchase of equipment payables mainly incurs for the construction of Suzhou production base.
- (iii) Amount due to a director was the talent introduction allowance temporarily received by the Group on behalf of Dr. Leung Shui On. The amount due thereto was fully settled on 6 January 2022.

Other payables and accrued expenses are non-interest-bearing and repayable on demand, or within 1 year.

## 10. INTEREST-BEARING BANK BORROWINGS

	<b>2021</b>	2020
	<b>RMB'000</b>	<b>RMB'000</b>
Bank loans repayable analysed into:		
Within one year	<b>5,000</b>	5,000
In the second year	<b>10,000</b>	5,000
In the third to fifth years, inclusive	<b>137,567</b>	40,000
Beyond five years	<b>46,210</b>	10,461
	<u><b>198,777</b></u>	<u>60,461</u>

*Note:*

- (i) In July 2019, the Group entered into an unsecured loan agreement with a reputable banking institution, which agreed to provide a credit facility of RMB200,000,000 for a term of nine years at a variable rate of interest equal to the People's Bank of China RMB Loan Prime Rate plus 0.25%, and the effective interest rate was 4.9% (2020: 4.9%) as of 31 December 2021. As at 31 December 2021, the amount of utilised facilities was RMB131,210,069 (2020: RMB60,460,553).
- (ii) In September 2021, the Group entered into a secured loan agreement with a reputable banking institution, which agreed to provide a credit facility of RMB500,000,000 for a term of ten years at a variable rate of interest equal to the People's Bank of China RMB Loan Prime Rate minus 0.30%, and the effective interest rate was 4.35% as of 31 December 2021. The bank loans borrowed by the Group are secured by the pledge of the Group's land use right, which had a net carrying value of approximately RMB15,503,000 at the end of the Reporting Period. As at 31 December 2021, the amount of utilised facilities was RMB67,566,794 (2020: Nil).

## 11. SHARE CAPITAL

	<b>2021</b>	2020
	<b>RMB'000</b>	<b>RMB'000</b>
Issued and fully paid:		
1,006,240,400 (2020: 1,006,240,400) ordinary shares	<u><b>1,679,126</b></u>	<u>1,679,126</u>

**PUBLICATION OF AUDITED CONSOLIDATED ANNUAL RESULTS AND 2021 ANNUAL REPORT ON WEBSITES OF STOCK EXCHANGE AND COMPANY**

This annual results announcement is published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.sinomab.com](http://www.sinomab.com)). The 2021 annual report of the Company containing all the information required by the Listing Rules will be despatched to the shareholders of the Company and published on the respective websites of the Stock Exchange and the Company in due course.

By order of the Board of  
**SinoMab BioScience Limited**  
**Dr. Shui On LEUNG**

*Executive Director, Chairman and Chief Executive Officer*

Hong Kong, 21 March 2022

*As at the date of this announcement, the executive Director is Dr. Shui On LEUNG, the non-executive Directors are Dr. Haigang CHEN, Mr. Xun DONG, Mr. Senlin LIU, Ms. Wenyi LIU, Ms. Jie LIU and Mr. Lei SHI and the independent non-executive Directors are Mr. George William Hunter CAUTHERLEY, Mr. Ping Cho Terence HON, Dr. Chi Ming LEE and Mr. Dylan Carlo TINKER.*