SINOMAB

中國抗體製藥有限公司
SinoMab BioScience Limited
（於香港註冊成立的有限公司）

Stock Code: 3681

2022 Interim Results

Quick Glance at SinoMab

The first Hongkong-based listed biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of therapeutics for the treatment of immunological diseases

Focuses on therapeutics platform for autoimmune diseases including "Antibody Humanisation Platform", "B cell therapeutic Platform", "Alarmins-pathway Therapeutic Platform", "Selective-T cell therapeutic Platform" and "Neurological Disease Platform"

Headquarters and R&D base in Hong Kong, Production base in mainland China, has commenced clinical trials in mainland China, Australia and the United States and set up companies

Vision: to become a global leader in the innovation of therapeutics for immunological and other debilitating diseases

01 Business Highlights

Our Pipeline

Pipeline	Indication	Territory	IND Enabling Stage I	IND Enabling Stage II	IND Enabling Stage III	Phase I	Phase II	Phase III	Launched
SM03 (anti-CD22) (First-in-Target)	*Rheumatoid arthritis (RA)	China							
	Non-Hodgkin's lymphoma (NHL)								
	Systemic lupus erythematosus (SLE)								
	Alzheimer's Diseases								
	Sjogren's syndrome (SS)								
SN1011 (BTK Inhibitor) (Third-Generation)	Pemphigus	China, US							
	Systemic lupus erythematosus (SLE)								
	Neuromyelitis Optica Spectrum Disorder (NMOSD)								
	Multiple Sclerosis (MS)								
SM17 (Humanised Anti-IL-17RB) (First-in-Class & First-in-Target)	Asthma	US, China							
	Atopic dermatitis (AD)								
	Idiopathic Pulmonary fibrosis (IPF)								
SM06 (Humanised Anti-CD22)	Systemic lupus erythematosus (SLE)	US, China							
	Rheumatoid arthritis (RA)								
	Neuromyelitis Optica Spectrum Disorder (NMOSD)								
	Sjogren's syndrome (SS)								
SM09 (Humanised Anti-CD20)	Non-Hodgkin's lymphoma (NHL)	China							
	Autoimmune Diseases								

*RA phase III completed recruitment in December 2021

IND enabling stage
IND enabling stage I - R&D
IND enabling stage II - chemistry, manufacturing and control processes（CMC）
IND enabling stage III - Preclinical

Completed study

Clinical stage

Flagship Product SM03

As of 31 December 2021, phase III clinical trial for RA has completed its enrollment of 530 patients, which is beyond the original target as 510 patients. The preliminary result for primary endpoint of Phase III study is expected in the third quarter of 2022, and the readout of the final study result for both safety and efficacy at week 52 is expected in the first quarter of 2023.

Plan to file NDA with the NMPA in the first half of 2023 and expect to commercialise SM03 upon health authority's approval in the second half of 2023 at the earliest.

Due to strategic prioritisation on specific therapeutic area other than RA, we expect to initiate proof-of-concept clinical studies for Alzheimer's disease and/or SS in China.

Key Product SN1011

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 PK profile.

An IND application of SN1011 for the treatment of SLE and pemphigus was also approved by the NMPA on 27 August 2020 and 23 June 2021 respectively.

Following SN1011 IND approval for pemphigus and SLE, a new IND submission in MS was submitted to the NMPA CDE in January 2022, and was approved by the NMPA in April 2022. A parallel IND application for MS is also scheduled for submission in the U.S in the third quarter of 2022, with a follow-up global Phase II clinical trial planned for initiation in the fourth quarter of 2022.

An IND application for NMOSD was also submitted and accepted by the CDE of the NMPA in June 2022. We plan to initiate the Phase II clinical study for NMOSD in China upon IND approval.

On 16 September 2021, the Company entered into a License Agreement with Suzhou Sinovent (together with the Company, as the licensor) and Everest HK (as the licensee) to out-license the right to develop and commercialize SN1011 globally for the treatment of renal diseases.

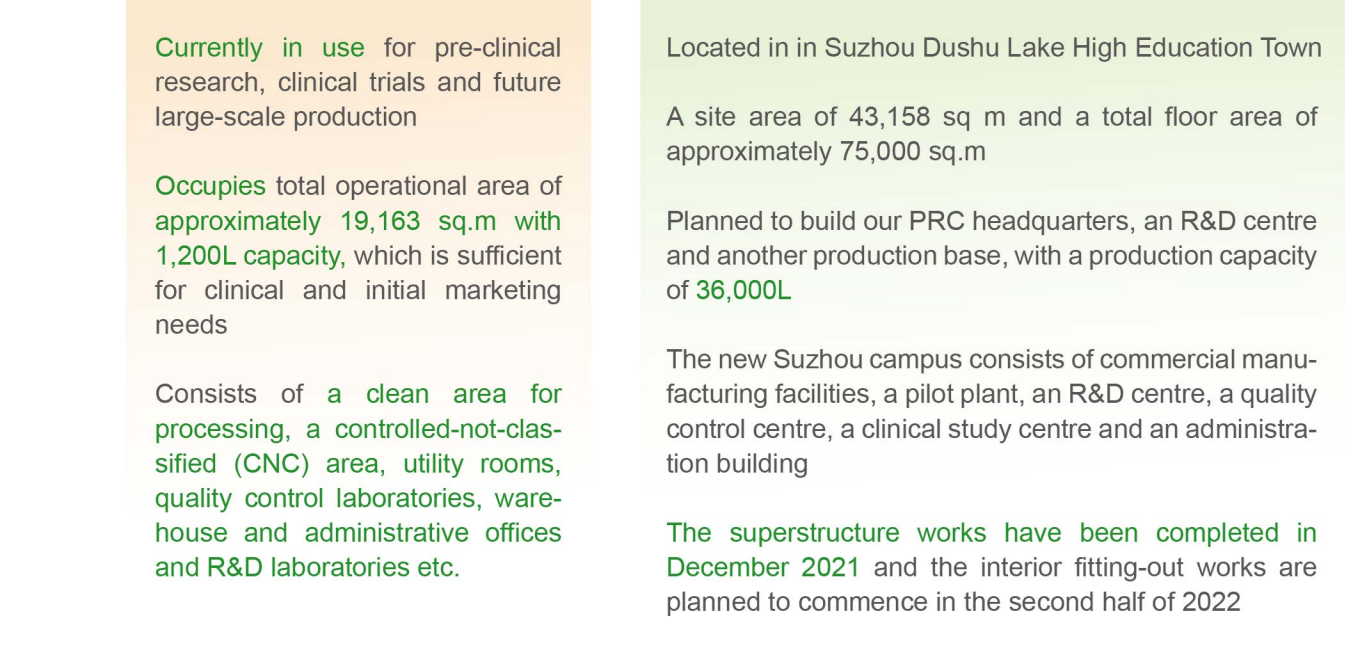
Key Product SM17

In February 2022, the IND submission was submitted and accepted by the FDA and was subsequently approved by the FDA in March 2022.

The first healthy subject had been successfully dosed in a Phase I First-in-Human (FIH) clinical trial in the U.S. in June 2022 and 14 subjects have been enrolled as of 31 July 2022. The subjects are currently in normal condition.

The Phase I clinical study consisting of SAD and MAD cohorts to evaluate its safety, tolerability, and PK in healthy subject.

Our Production Base



Haikou Production Base

Currently in use for pre-clinical research, clinical trials and future large-scale production

Occupies total operational area of approximately 19,163 sq.m with 1,200L capacity, which is sufficient for clinical and initial marketing needs

Consists of a clean area for processing, a controlled-not-classified (CNC) area, utility rooms, quality control laboratories, warehouse and administrative offices and R&D laboratories etc.

PRC Headquarters (Suzhou)

Located in in Suzhou Dushu Lake High Education Town

A site area of 43,158 sq m and a total floor area of approximately 75,000 sq.m

Planned to build our PRC headquarters, an R&D centre and another production base, with a production capacity of 36,000L

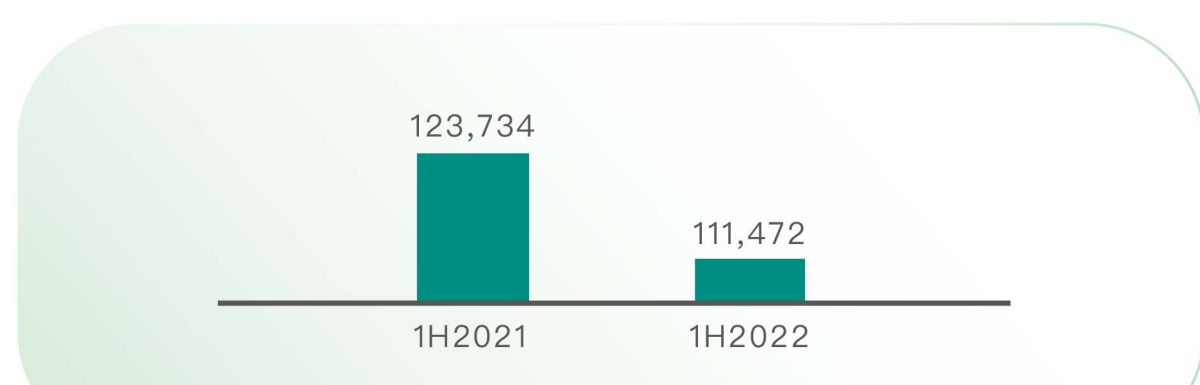
The new Suzhou campus consists of commercial manufacturing facilities, a pilot plant, an R&D centre, a quality control centre, a clinical study centre and an administration building

The superstructure works have been completed in December 2021 and the interior fitting-out works are planned to commence in the second half of 2022

Phase I development with a production capacity of 6,000L is expected to come into operation in early 2024

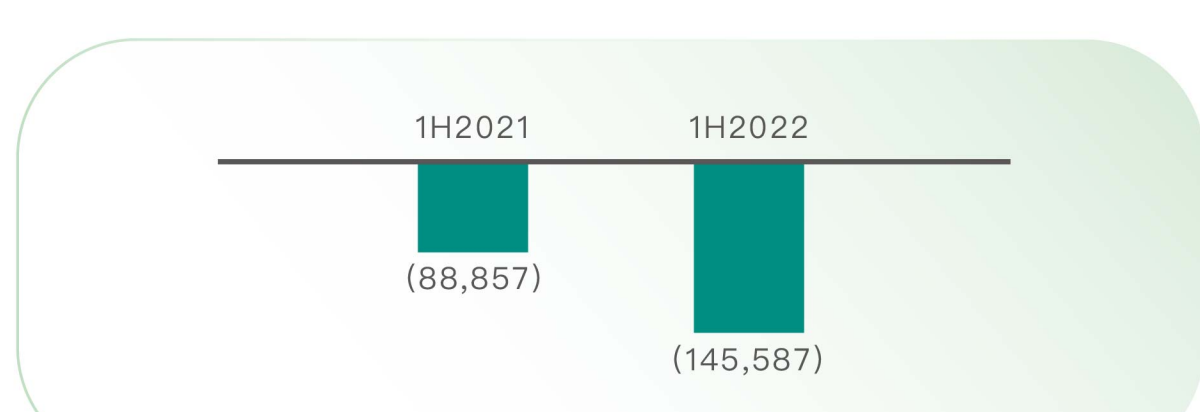
02 Financial Performance

Total comprehensive loss



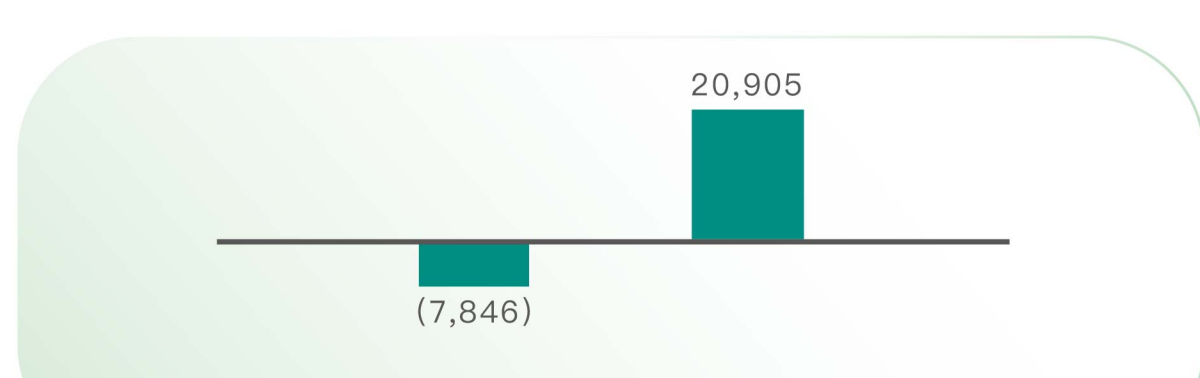
RMB '000

Net cash flows used in operating activities



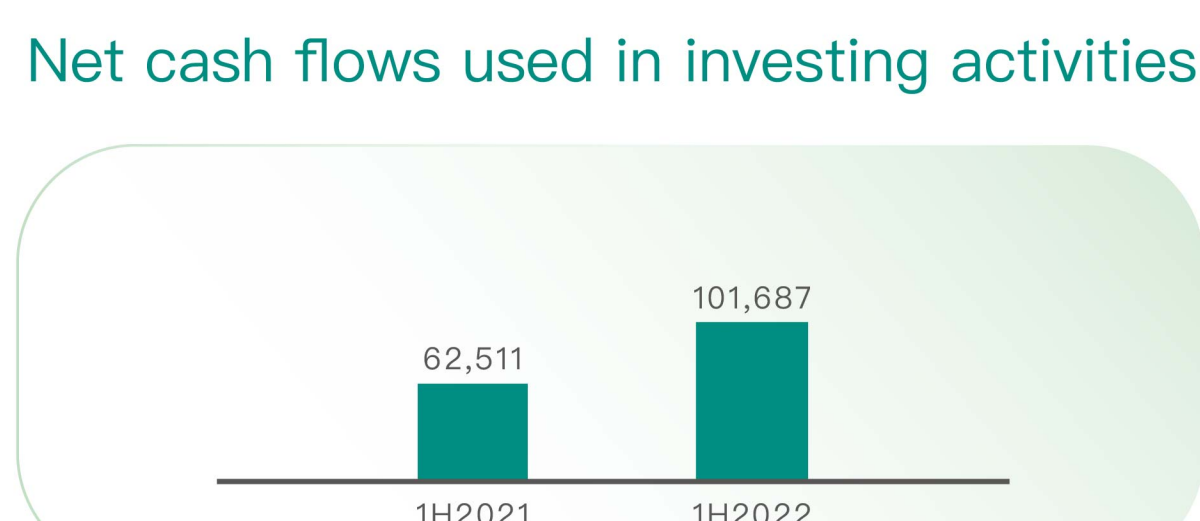
RMB '000

Net cash flows used in financing activities



RMB '000

Net cash flows used in investing activities

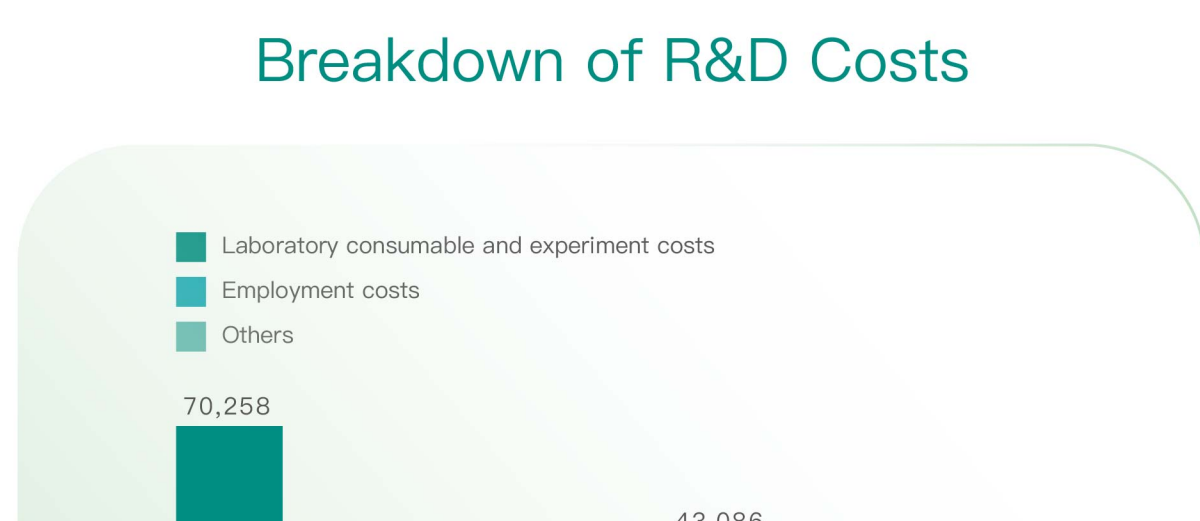


RMB '000

R&D Costs

RMB '000

Breakdown of R&D Costs



RMB '000

03 Future Strategies

Strategic Layout

One of a few biopharmaceutical companies based in Hong Kong

Established full-spectrum platform integrating in-house capabilities across the industry chain

Strong R&D strength enable us an ideal partner for reputable companies and institutions. Entered into a long-term collaboration with D2M Biotherapeutics Limited for the identification of novel drug targets.

Well-prepared for commercialization backed by production facilities and sales team to be assembled

Commercialisation

Expect to build up our sales team by 2022, the leader of sales and marketing was on board in February 2022

Covering a majority of provinces and municipalities in China to support the future commercialization of our drug candidates

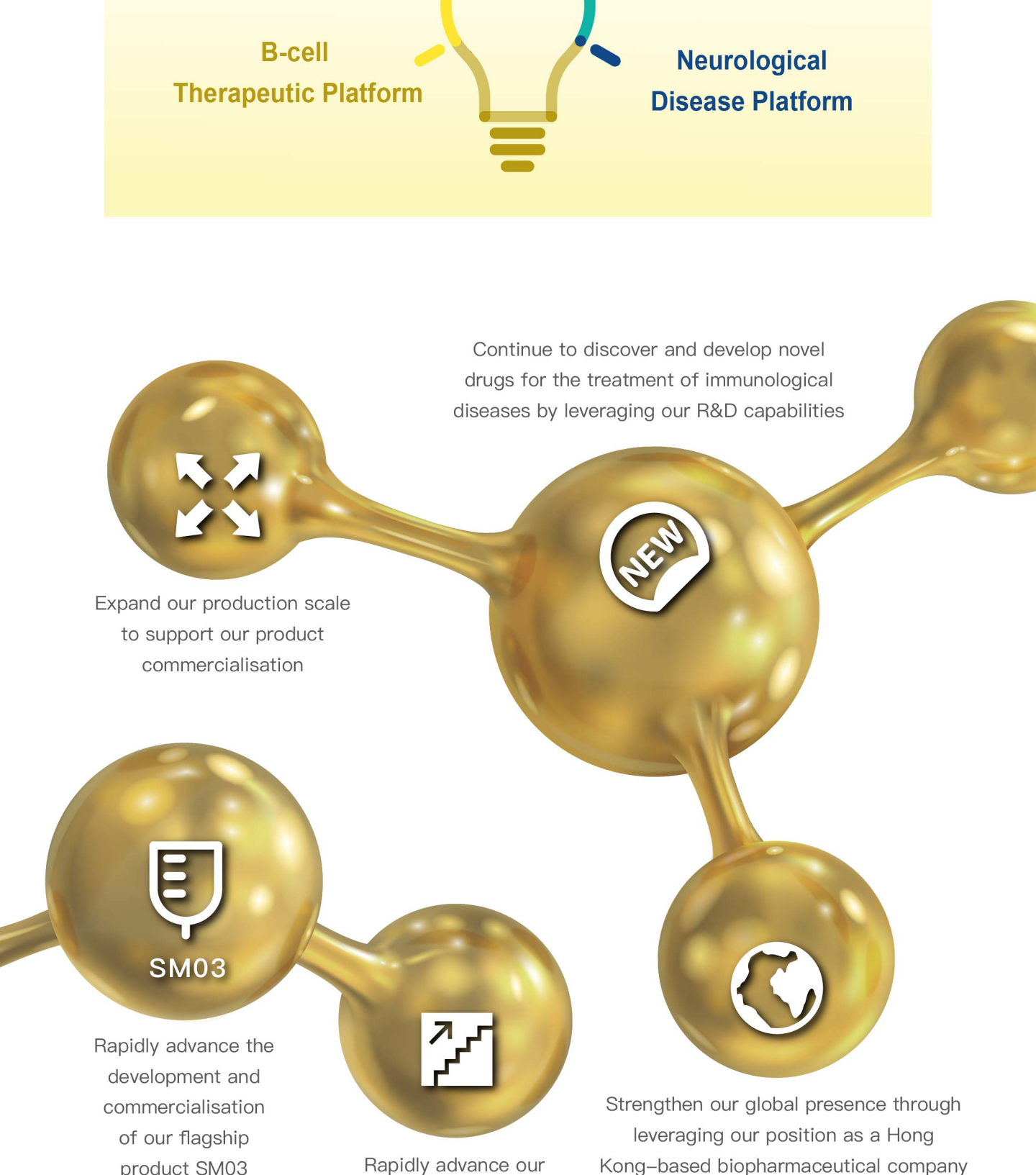
Actively exploring and identifying opportunities for collaboration or partnership, including but not limited to licencing in or licencing out

2021 | 2022 | ...

Albeit uncertainties associated with COVID-19, we expect to build up our sales team by 2022.

Development Strategies

We are committed to establishing ourselves as a global leader in the innovation of therapeutics for immunological diseases.



The Company has always been committed to researching and developing monoclonal antibody drugs in the field of autoimmune diseases. With the original aspiration, we will remain dedicated to discovering and developing novel drugs, advancing innovative treatments for autoimmune diseases to fight for patients' well-being and create value for shareholders.

Dr. Shui On LEUNG
Chairman, Executive Director and Chief Executive Officer