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

2021 Annual Results

Quick Glance at SinoMab

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

Focuses on therapeutics platform for autoimmune diseases including "B cell therapeutic platform", "Alarmins therapeutic platform", and the developing "T cell therapeutic platform"

R&D base in Hongkong, 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
SM03 (anti-CD22) (First-in-Target)	*Rheumatoid arthritis (RA); Non-Hodgkin's lymphoma (NHL); Systemic lupus erythematosus (SLE); Systemic lupus erythematosus (SLE); Alzheimer's Diseases (AD)	China
SN1011 (BTK Inhibitor) (Third-Generation)	Pemphigus; Systemic lupus erythematosus (SLE); Multiple Sclerosis (MS); Neuromyelitis Optica Spectrum Disorder (NMOSD)	China; US
SM17 (Humanised Anti-IL17RB) (First-in-Class & First-in-Target)	Asthma; Atopic dermatitis (AD); Idiopathic Pulmonary fibrosis (IPF)	US; China
SM06 (Humanised Anti-CD22)	Systemic lupus erythematosus (SLE); Rheumatoid arthritis (RA); Neuromyelitis Optica Spectrum Disorder (NMOSD); Sjogren's syndrome (SS)	US; China
SM09 (Humanised Anti-CD20)	Non-Hodgkin's lymphoma (NHL); Autoimmune Diseases	China
TNF2 (Humanised Ab)	Autoimmune Diseases	China

Columns: IND Enabling (Stage I, Stage II, Stage III), Phase I, Phase II, Phase III, Launched

*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 primary analysis readout is expected in the third quarter of 2022.

Plan to file New Drug Application ("NDA") with NMPA in the first half of 2023.

Expect to initiate Phase II clinical study for SLE in the second half of 2022 to broaden the therapeutic uses of SM03.

Expect to commercialize SM03 by the second half of 2023.

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.

On 23 June 2021, an IND application for the treatment of pemphigus vulgaris (PV) was also approved by the NMPA which is the first BTK inhibitor known for the treatment of PV in China in clinical stage with huge unmet clinical needs.

Following SN1011 IND approval for Pemphigus and SLE, 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.**

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. **A global phase II trial in multiple sclerosis (MS) is planning in both China and the US in the third quarter of 2022.**

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-in-Human (FIH) phase I 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.

Our Production Base

Haikou Production Base

Currently in use for producing clinical drugs

Expanded its total operational area from approximately 4,526 sq. m to approximately 19,163 sq.m with 1,200L capacity, which is sufficient for clinical and initial marketing needs

Consists of a clean area, a controlled-not-classified (CNC) area, utility rooms, quality control laboratories, etc.

PRC Headquarters (Suzhou)

Located in Suzhou Dushu Lake High Education Town, with a total floor area of approximately 75,000 sq.m

Plan to build an R&D centre and a production base, with a production capacity over 32,000L

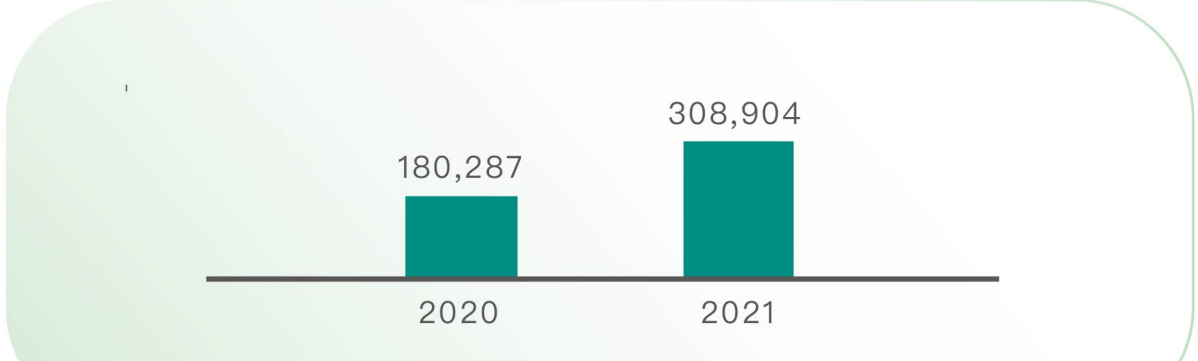
The new Suzhou campus consists of a manufacturing shop, a pilot plant, an R&D centre, a quality inspection centre, a clinical study centre and an administration building

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

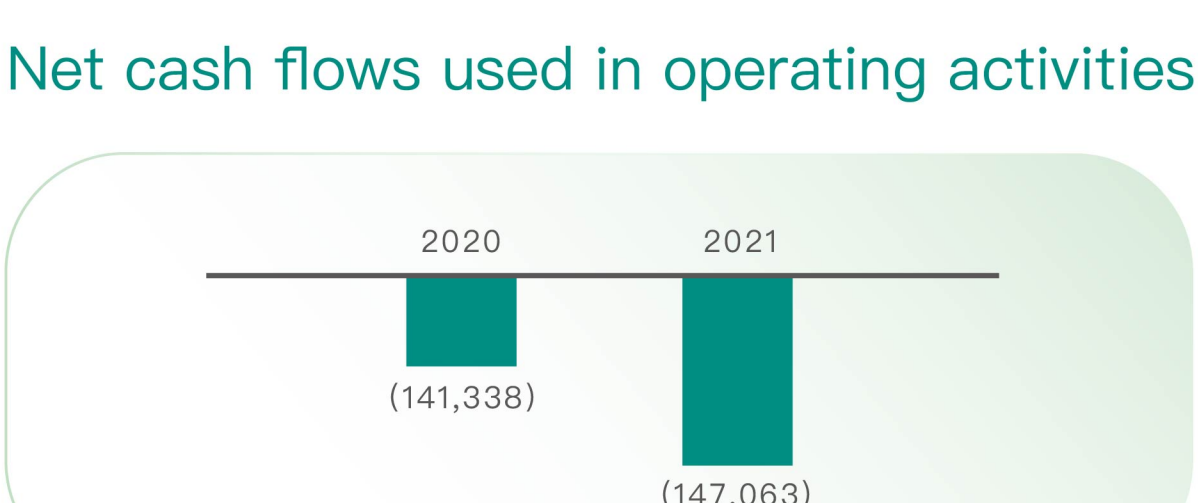
Phase I development with a production capacity of 6,000L is expected to come into operation in early 2023

02 Financial Performance

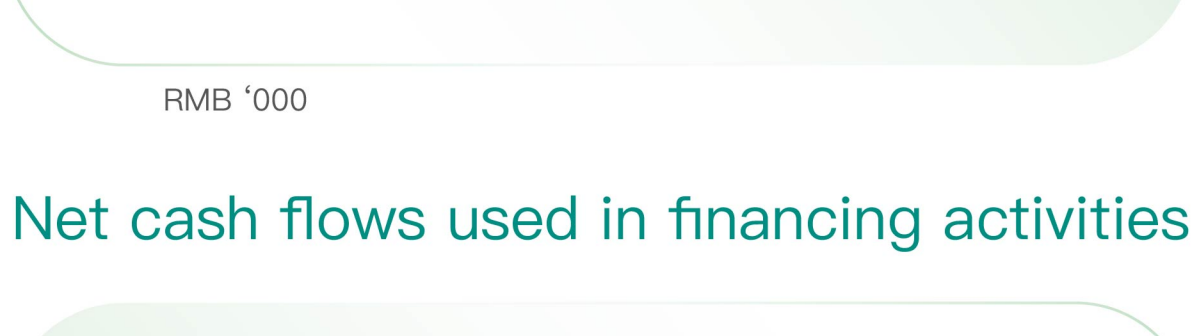
Total comprehensive loss



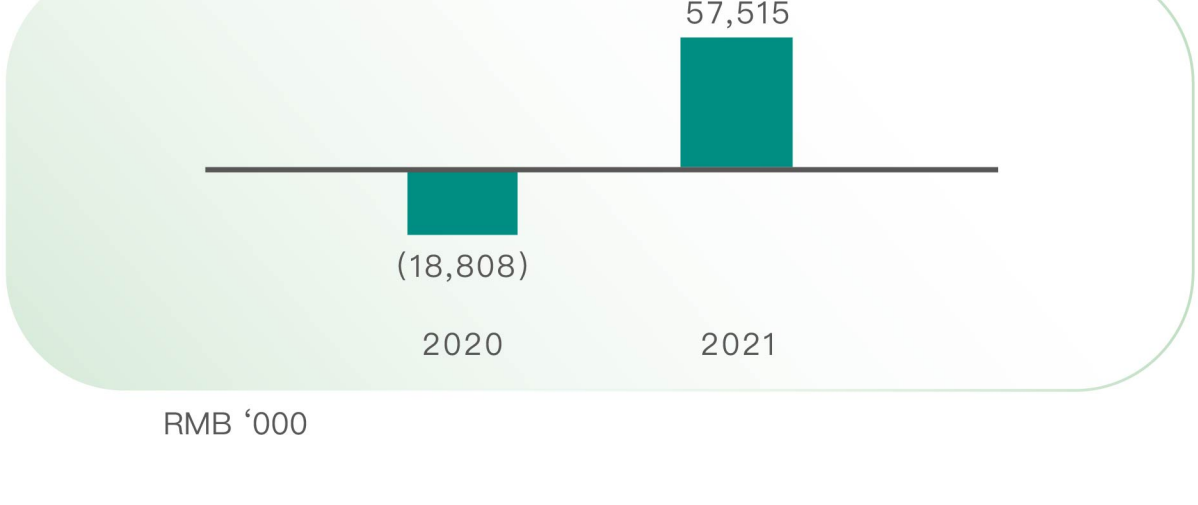
Net cash flows used in operating activities



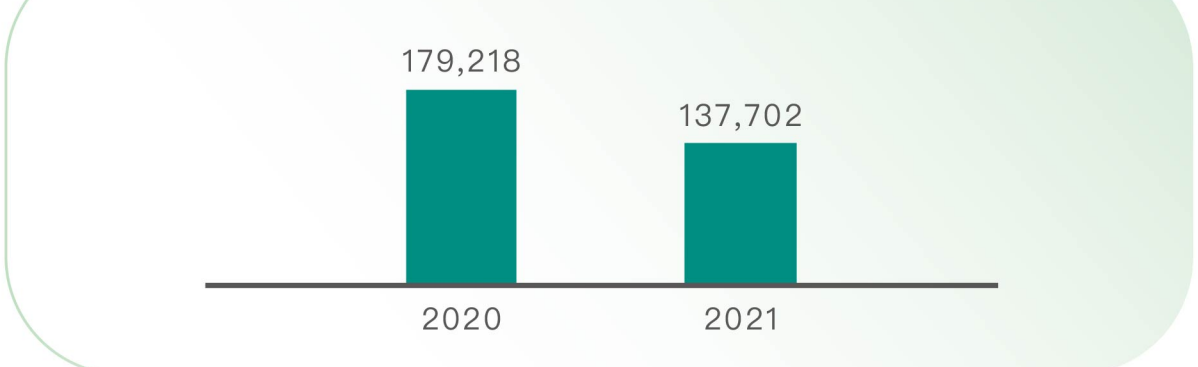
Net cash flows used in financing activities



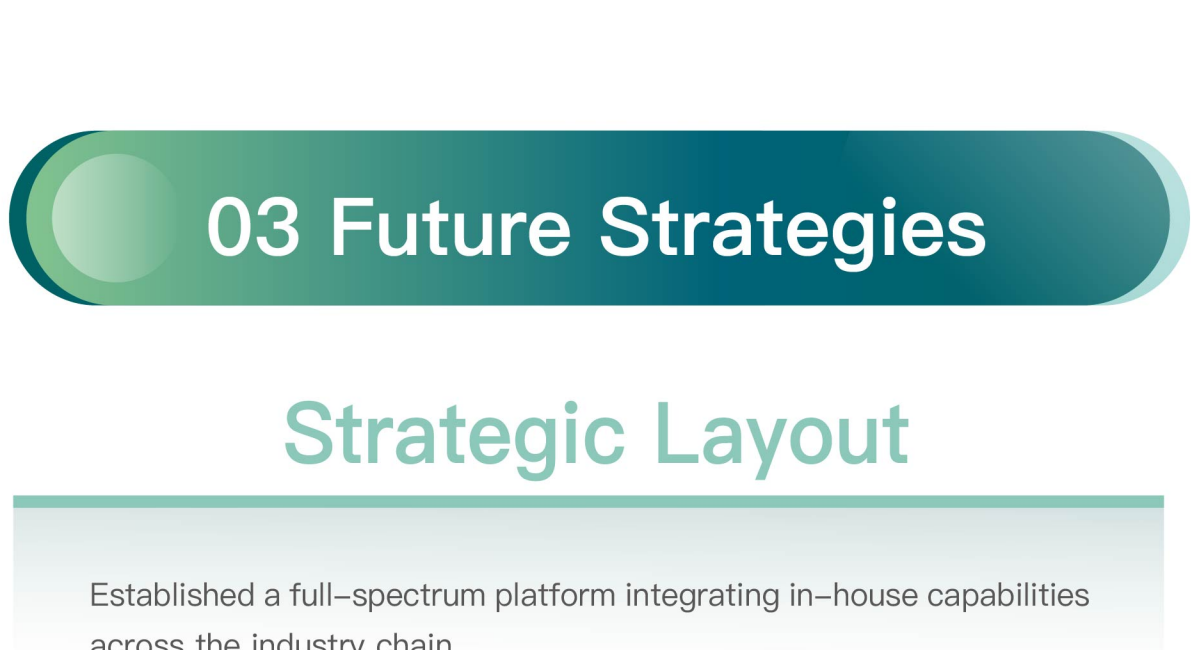
Capital expenditure



R&D Costs



Breakdown of R&D Costs



03 Future Strategies

Strategic Layout

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

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 a 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

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

2021 — 2022 — ...

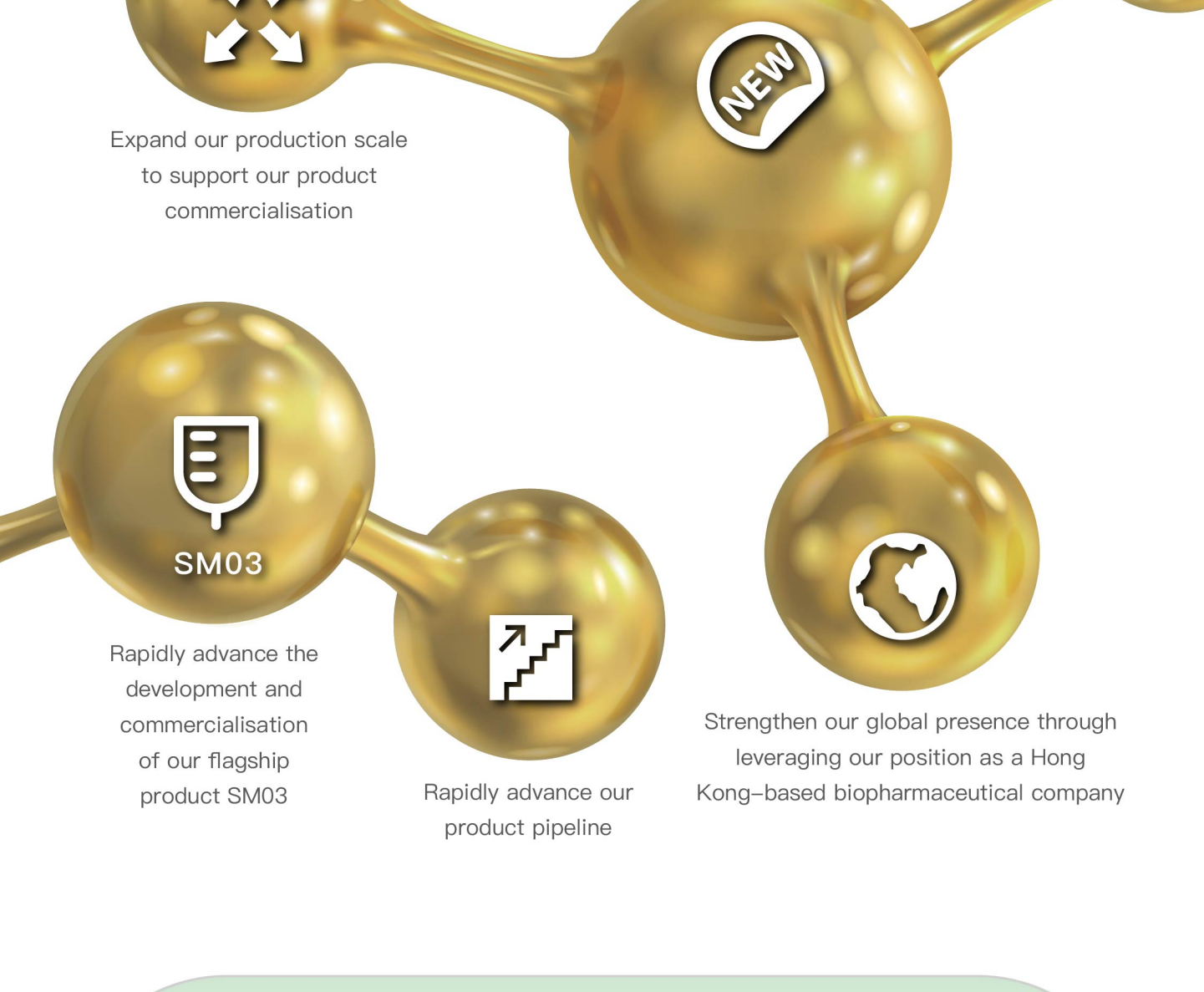
Albeit uncertainties associated with COVID-19, we expect to build up our sales team by 2022.

Development Strategies

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

Innovative B cell therapeutic platform

Innovative Alarmins pathway therapeutic platform



In its 20 years of history, the Company has been committed to antibody R&D. With the original aspiration, we will remain dedicated to discovering and developing novel drug targets, advancing treatments for immunological diseases to fight for patients' well-being; continue to explore cooperation opportunities, consolidate our position in the capital market and fulfil the commitments to shareholders and the society.

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