



邁博藥業

MABPHARM LIMITED

邁博药业有限公司

(Incorporated in the Cayman Islands with limited liability)

Stock Code : 2181



2021

INTERIM REPORT

The background features a large, stylized 'Y' logo in the center, surrounded by various scientific and medical icons such as DNA helices, microscopes, test tubes, and human figures. The overall color scheme is a warm, light orange.

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Corporate Information

BOARD OF DIRECTORS

Executive Directors

Dr. Wang Hao (*Chief Executive Officer*)
Mr. Li Yunfeng
Dr. Li Jing
Mr. Tao Jing

Non-executive Directors

Mr. Jiao Shuge (*Chairman*)
Mr. Guo Jianjun

Independent Non-executive Directors

Mr. Guo Liangzhong
Dr. Zhang Yanyun
Dr. Liu Linqing

AUDIT COMMITTEE

Dr. Liu Linqing (*Chairman*)
Mr. Jiao Shuge
Mr. Guo Liangzhong

REMUNERATION COMMITTEE

Dr. Zhang Yanyun (*Chairman*)
Dr. Wang Hao
Mr. Guo Liangzhong

NOMINATION COMMITTEE

Mr. Guo Liangzhong (*Chairman*)
Mr. Tao Jing
Dr. Zhang Yanyun

JOINT COMPANY SECRETARIES

Mr. Li Yunfeng
Mr. Tsang Ho Yin

AUTHORIZED REPRESENTATIVES

Mr. Li Yunfeng
Mr. Tsang Ho Yin

REGISTERED OFFICE IN CAYMAN ISLANDS

Walkers Corporate Limited
190 Elgin Avenue
George Town
Grand Cayman KY1-9008
Cayman Islands

PRINCIPAL PLACE OF BUSINESS AND HEAD OFFICE IN THE PRC

Block G79
Lujia Road East
Koutai Road West
China Medical City Taizhou
PRC
225300

PRINCIPAL PLACE OF BUSINESS IN HONG KONG

Room A, 18/F, Hong Xiang Centre
83 Queen's Road East
Wanchai
Hong Kong

AUDITOR AND REPORTING ACCOUNTANT

Ernst & Young

Certified Public Accountants
Registered Public Interest Entity Auditor
27/F, One Taikoo Place
979 King's Road
Quarry Bay
Hong Kong

LEGAL ADVISORS

As to Hong Kong law

Stevenson, Wong & Co.
39/F, Gloucester Tower, the Landmark
15 Queen's Road
Central
Hong Kong

As to PRC law

Shanghai Allbright (Shenzhen) Law Offices
23rd Floor, Tower 1,
Excellence Century Centre,
Fu Hua 3rd Road
Futian District,
Shenzhen
PRC

HONG KONG SHARE REGISTRAR

Computershare Hong Kong Investor Services
Limited
Shops 1712-1716, 17/F
Hopewell Centre
183 Queen's Road East
Wanchai
Hong Kong

PRINCIPAL SHARE REGISTRAR AND TRANSFER OFFICE IN CAYMAN ISLANDS

Walkers Corporate Limited
190 Elgin Avenue
George Town
Grand Cayman KY1-9008
Cayman Islands

PRINCIPAL BANK

Shanghai Pudong Development Bank
(Medical High-Tech Zone Branch)
1/F, Data Building, Taizhou Avenue
Medical High-Tech Zone
Taizhou, Jiangsu
PRC

STOCK CODE

2181

COMPANY WEBSITE

www.mabpharm.cn

Financial Highlights

For the six months ended June 30,

	2021 <i>RMB'000</i> (unaudited)	2020 <i>RMB'000</i> (unaudited)	Change (%) (unaudited)
Revenue	81,246	–	–
Cost of sales	(16,769)	–	–
Gross profit	64,477	–	–
Other income	3,558	20,939	(83.0)
Other gains and losses	(4,719)	19,066	(124.8)
Research and development expenses	(163,455)	(60,828)	168.7
Administrative expenses	(43,755)	(30,741)	42.3
Finance costs	(1,267)	(2,624)	(51.7)
Loss before tax	(145,161)	(54,188)	167.9
Income tax expense	–	–	–
Loss and total comprehensive expense for the period	(145,161)	(54,188)	167.9
Attributable to:			
Owners of the Company	(145,161)	(54,188)	167.9
Loss per share attributable to ordinary equity holders of the Company			
– Basic	RMB(0.04)	RMB(0.01)	
– Diluted	RMB(0.04)	RMB(0.01)	

	At June 30, 2021 <i>RMB'000</i> (unaudited)	At December 31, 2020 <i>RMB'000</i> (audited)	Change (%) (unaudited)
Non-current assets	580,663	593,911	(2.2)
Current assets	397,962	569,126	(30.1)
Current liabilities	191,830	202,627	(5.3)
Net current assets	206,132	366,499	(43.8)
Non-current liabilities	43,901	78,925	(44.4)
Net assets	742,894	881,485	(15.7)

Corporate Profile

We are a leading biopharmaceutical company in China, focusing on the research, development and production of new drugs and biosimilar for cancers and autoimmune diseases. We strive to bring to the market high quality and affordable innovative biologics through our efficient research and development (“**R&D**”) system and low-cost pharmaceutical production capabilities, and develop differentiated therapeutic products by fully utilizing our extensive R&D experience. Our drug pipeline currently consists of 10 monoclonal antibody drugs and 1 strong antibody drug:

- **CMAB008 類停® (infliximab)**: was approved for marketing by the National Medical Products Administration of the People’s Republic of China (“**NMPA**”) in July 2021 (Guo Yao Zhun Zi S20210025) for the treatment of 1) ulcerative colitis in adults; 2) ankylosing spondylitis; 3) rheumatoid arthritis; 4) Crohn’s disease in adults and pediatric patients aged above 6 years old; 5) fistula Crohn’s disease; and 6) psoriasis. The antibody drug production base of Taizhou Mabtech Pharmaceutical Limited (泰州邁博太科藥業有限公司) under the Company in China Medical City, Taizhou, Jiangsu Province also successfully passed the GMP compliance inspection for CMAB008 by Jiangsu Provincial Drug Administration. According to the regulations of China’s basic medical insurance program (the “**Medical Insurance**”), CMAB008 類停® has also been automatically included in the Medical Insurance, and has obtained the Medical Insurance registration code from the National Healthcare Security Administration (the “**Healthcare Security Administration**”). CMAB008 類停® is approved for the treatment of six indications which have huge long-term unmet market demand (with more than 10 million patients in the PRC which is still growing). With high quality innovative drugs as the foundation, Mabpharm will provide innovative antibody drugs to patients in the PRC by offering more economical and affordable drug supply solutions and fully participating in China’s national healthcare system reform initiatives. The Company has also initiated cooperation with partners who have accumulated abundant overseas market resources over a long period of time to rapidly expand to overseas markets.

As announced by the World Health Organization (the “**WHO**”) recently, WHO has launched a global clinical trial of drugs including infliximab for the treatment of novel coronavirus pneumonia (“**COVID-19**”) – the “Solidarity PLUS” according to the previous clinical application with reference to the evaluation conducted by independent expert committee. The Company also proposes to work with its partners to promote the clinical trials of CMAB008 類停® (infliximab) in foreign countries that have been seriously affected by the COVID-19 pandemic (the “**Pandemic**”) for the treatment of COVID-19, and will proactively respond to the anti-COVID-19 call of the PRC government.

- **CMAB007 (omalizumab)**: completed phase III clinical trials for the indication of asthma and new drug application data collation. The new drug marketing application for CMAB007 is expected to be submitted to the NMPA in September 2021. Given that similar drugs have been approved overseas for urticaria and allergic rhinitis indications and are developing to address food allergy indications, we will expedite the clinical and registration work of CMAB007 for these indications to capture the huge allergic disease market demand in China;

Corporate Profile

- **CMAB009 (cetuximab)**: currently under phase III clinical trials for colorectal cancer. CMAB009 uses the Chinese hamster ovary cell (“**CHO**”) expression system, which enjoys significant advantages in safety compared to existing marketed cetuximab products for treating metastatic colorectal cancer. CMAB009 is expected to file the new drug marketing application with the NMPA in the third quarter of 2022;
- **CMAB807 (denosumab)**: currently under phase III clinical trials for osteoporosis. We are conducting pre-clinical research of the drug for the indication of tumor bone metastasis and will submit the clinical trial application to the Center for Drug Evaluation of NMPA in the fourth quarter of 2021.

Among our other drug candidates, our newly developed “strong antibody” drug CMAB017 has completed the pilot scale up and commenced animal experiments. The completed research results show that CMAB017 has promising efficacy and safety. In addition, we have commenced clinical trials for CMAB819 (nivolumab). We have also developed CMAB022 (usnumab), a biosimilar drug, which has a good market prospect in the fields of psoriasis, ankylosing spondylitis and Crohn’s disease.

We have strong in-house capabilities in pharmaceutical research, manufacturing and pre-clinical and clinical development, and have established a competent and efficient drug marketing team. We focus on the R&D of monoclonal antibodies. Our core R&D team members have more than 18 years of experience in this area, and have led three major projects under the “863” Program, among other national-level scientific research projects. In addition, one of our core R&D team members is also a member of the 11th Session of the Chinese Pharmacopoeia Commission.

We have completed the construction of three new production lines in Taizhou, bringing our total cell reactor scale to 18,000 liters. The construction of plants in our new R&D and industrial base in Taizhou has also been completed and it is expected that our total cell reactor scale will be further increased to above 40,000 liters in 2022. The solid equipment, technology and quality foundation we have in the field of antibody drug preparation will enable us to possess an excellent competitive advantage in future medical insurance and centralized procurement negotiations.

We believe that we are well positioned to seize China’s substantial market opportunities, in particular those resulting from China’s recent healthcare regulatory reforms, including new medical insurance measures. The primary focus of our R&D – monoclonal antibody drugs targeting cancers and autoimmune diseases – has substantial untapped clinical demand in China.

Further, during the rapid growth of the pharmaceutical market in China, the central procurement under the medical insurance that may be extended to cover biological drugs in the future and the increased efforts in national negotiations on medical insurance will restructure the pharmaceutical market in China to a large extent. We will actively participate in the national medical reform with our advantages in advanced technology, quality and cost and capture the opportunities presented during the policy reform so as to capture the huge unmet market demand in China. At the same time, we have also initiated our global market expansion and accelerated the registration and launching of our drugs in the international market.

Management Discussion and Analysis

BUSINESS REVIEW

Research and development of our drug candidates

Set out below is an overview of our drug candidates and their R&D status as of June 30, 2021:

Field	Target	Indication	Drug candidate code	Classification	Pre-clinical	Phase I	Phase II or Phase III/III	Phase III	Expected time to reach the next regulatory milestone	Anticipated completion of regulatory review	Commercial rights	Competitive marketed drugs
Autoimmune Disease	TNF α	Ulcerative colitis in adults; Ankylosing spondylitis; Rheumatoid arthritis; Crohn's disease in adults and pediatric patients aged above 6 years old; Fibrosis; Crohn's disease; and Psoriasis	CMAB008 (INN name: Infliximab)	Biosimilar/Core Product					Not applicable	New drug application approved in July 2021	PRC and overseas (excluding Japan, North America and Europe)	Remicade®, Humira®, Enbrel®, Simponi®, Yisiplo® and Anbenuo®
Respiratory Disease	IgE	Asthma	CMAB007 (INN name: Omalizumab)	New Drug/Core Product					Pending marketing application submission (Quarter 3, 2021)	Quarter 4, 2022	PRC and overseas (excluding Japan, North America and Europe)	Xolair®
Cancer	EGFR	Colorectal cancer	CMAB009 (INN name: Cetuximab)	New Drug/Core Product					Pending marketing application submission (Quarter 3, 2022)	Quarter 3, 2023	PRC and overseas (excluding Japan, North America and Europe)	Erbivud®
Bone-related diseases	RANKL	Osteoporosis	CMAB807 (INN name: Denosumab)	Biosimilar					Pending marketing application submission (Quarter 1, 2023)	Quarter 1, 2024	Global	Prolia®
		Tumor bone metastasis	CMAB807X (INN name: Denosumab)	Biosimilar					Phase III (Quarter 1, 2023)	Quarter 1, 2027	Global	XGEIVA®

Management Discussion and Analysis

Field	Target	Indication	Drug candidate code	Classification	Pre-clinical	Phase I	Phase II or Phase III/III	Phase III	Expected time to reach the next regulatory milestone	Anticipated completion of regulatory review	Commercial rights	Competitive marketed drugs
Cancer	PD1	Non-small cell lung cancer, hepatocellular carcinoma and squamous cell carcinoma of the head and neck	CMAB019 (INN name: Nivololumab)	Biosimilar				Phase III (Quarter 1, 2023)	Quarter 4, 2027	Global	Global	Opdivo® Keytruda® Tyvyt® JS001
Cancer	HER2	Breast cancer	CMAB010 (INN name: Pertuzumab)	Biosimilar				Phase III (Quarter 1, 2024)	Quarter 1, 2028	Global	Global	Perjeta®
Cancer/Autoimmune Disease	IL-1β	Periodic Fever Syndromes/ Systemic Juvenile Idiopathic Arthritis/Lung cancer	CMAB016 (INN name: Canakinumab)	Biosimilar				Phase III (Quarter 2, 2024)	Quarter 2, 2026	Global	Global	Ilaris®
Cancer	EGFR	KRAS wild-type colorectal cancer	CMAB017	Innovative drug				Phase III (Quarter 4, 2024)	Quarter 4, 2027	Global	Global	Vectibix®
Autoimmune Disease	IL-17A	Plaque psoriasis, psoriatic arthritis and ankylosing spondylitis	CMAB015 (INN name: Secukinumab)	Biosimilar				Phase III (Quarter 1, 2023)	Quarter 2, 2026	Global	Global	Cosentyx®
Allergy, Inflammatory Disease	IL-5	Asthma and eosinophilic granulomatous polyangitis	CMAB018 (INN name: Mepolizumab)	Biosimilar				Phase III (Quarter 2, 2023)	Quarter 4, 2026	Global	Global	Nucala®
Inflammatory Diseases	IL-12 & IL-23	Moderate to severe plaque psoriasis, psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis	CMAB022 (INN name: Ustekinumab)	Biosimilar				Phase III (Quarter 1, 2024)	Quarter 1, 2027	Global	Global	Stelara®

Cautionary Statement required by Rule 18A-08(3) of the Listing Rules: We may not be able to ultimately develop and market our drug candidates (including Core Products) successfully.

Core Products

類停®-CMAB008 (infliximab)

CMAB008 (infliximab), trade name: 類停®, is a recombinant anti-TNF-alpha chimeric monoclonal antibody that was approved by the NMPA (Guo Yao Zhun Zi S20210025) on July 12, 2021 for the treatment of:

- (i) ulcerative colitis in adults;
- (ii) ankylosing spondylitis;
- (iii) rheumatoid arthritis;
- (iv) Crohn's disease in adults and pediatric patients aged above 6 years old;
- (v) fistula Crohn's disease; and
- (vi) psoriasis.

CMAB008 類停® is the first China-made infliximab approved for marketing, which is a monoclonal antibody biosimilar independently developed by the Company and one of the core products of the Company. CMAB008 類停® uses the CHO expression system, and is a monoclonal antibody targeting TNF α (tumor necrosis factor α) that specifically merges with TNF α and blocks the inflammatory cascade response caused by TNF α . The researches we have completed have shown that, compared to other anti-TNF α drugs on the market, CMAB008 類停® (infliximab for injection) has a stronger affinity for TNF α and a stronger glycosylation character, with rapid onset of effect, long-lasting efficacy, long dosing intervals and no hypersensitivity reactions. The results of our completed researches including, clinical trials, non-clinical comparative studies and pharmacological comparisons of CMAB008 類停® have also shown that CMAB008 is identical to the original infliximab in terms of efficacy, safety, pharmacological profile and quality.

Management Discussion and Analysis

The only other infliximab currently available for sale in the PRC is “Remicade”, an imported drug sold by Xian Janssen. CMAB008 類停® is approved for the treatment of six indications which have huge long-term unmet market demand with more than 10 million patients in the PRC which is still growing. Infliximab is included in the PRC’s national Medical Insurance drug catalogue, and in accordance with relevant regulations on Medical Insurance of the PRC, our CMAB008 類停® is applicable to the Medical Insurance coverage of infliximab, thus providing a new and more economical and affordable option for patients. With high quality innovative drugs as the foundation, Mabpharm will provide innovative antibody drugs to patients in the PRC by offering more economical and affordable drug supply solutions and fully participating in China’s national healthcare system reform initiatives. The Company has also reached agreements with partners who have accumulated abundant overseas market resources over a long period of time and is applying for drug registration and marketing of CMAB008 in dozens of countries and regions including Brazil.

On August 11, 2021, the WHO announced that the “Solidarity PLUS” campaign led by it would recruit hospitalized COVID-19 patients to evaluate the efficacy of three drugs, being artesunate, imatinib and infliximab, in treating diseases caused by the novel coronavirus (the “**Novel Coronavirus**”) from more than 600 hospitals across 52 countries and regions. These three drugs were selected by an independent expert group and considered to have the potential to reduce the mortality rate of hospitalized COVID-19 cases. “Cytokine storm” is an important cause of severe pneumonia and failure of multiple organs resulting from the Novel Coronavirus, and TNF α (tumor necrosis factor α) and other inflammation-related cytokines are significantly increased in severe COVID-19 cases. For severe COVID-19 cases, it may take too long for antiviral drugs to take effect, and they are more likely to benefit from drugs targeting the immune system. Infliximab can block the inflammatory signaling pathway of TNF α and reduce the level of inflammatory cytokines such as TNF α . The data collected from patients with inflammatory bowel disease who received anti-TNF treatment such as infliximab in Germany showed that the mortality of such patients after being infected with the Novel Coronavirus was far below the average level. The results of infliximab treatment for severe COVID-19 patients without inflammatory bowel disease also proved that the mortality rate was significantly lower than that of the control group. In this regard, the Company proposes to work with its partners to promote the clinical trials of CMAB008 類停® (infliximab) in foreign countries that have been affected seriously by the COVID-19 pandemic, and will proactively respond to the anti-COVID-19 call of the PRC government.

Recently, CMAB008 has been approved by the NMPA. Please refer to the section headed “SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD” below for further details.

CMAB007 (omalizumab)

CMAB007 (omalizumab), a recombinant humanized anti-IgE monoclonal antibody, is our new drug candidate for treatment of asthma patients who remain inadequately controlled despite med/high dose of ICS plus LABA. We believe that, once approved by the NMPA for marketing, it will be the first mAb asthma therapy developed by a local Chinese company marketed in China. CMAB007 combines with free IgE to form an anti-IgE complex that inhibits the high affinity IgE receptor and thereby prevents the allergic response. The safety and efficacy of CMAB007 have been confirmed by the results of four clinical trials of a total of 824 subjects who have been administered CMAB007, which were the largest clinical trials of mAb treating asthma in China. Based on our clinical trial results, CMAB007 can improve asthma patients' conditions with lower-dose inhaled corticosteroids and reduce the incidence of acute asthma attacks.

During the Reporting Period, CMAB007 has completed phase III clinical trials for allergic asthma. Based on new regulations and technical guidelines introduced by the NMPA on new biological drugs, we have also completed a head-to-head phase I comparative study against currently marketed omalizumab products to confirm the similar pharmacokinetic profile and immunogenicity of CMAB007. It is expected that CMAB007 will expand its indications to chronic idiopathic urticarial, seasonal allergic rhinitis and food allergies in the future. We plan to file the drug marketing application with the NMPA in the third quarter of 2021. Currently, we expect that CMAB007 may be approved by the NMPA for marketing in the fourth quarter of 2022.

CMAB009 (cetuximab)

CMAB009 (cetuximab), a recombinant anti-EGFR chimeric monoclonal antibody, is our new drug candidate based on cetuximab for first-line treatment of metastatic colorectal cancer ("**mCRC**") in combination with FOLFIRI. CMAB009 is the first NMPA approved chimeric anti-EGFR antibody for clinical trial developed in China by a local Chinese company. CMAB009 uses the CHO expression system, which is different from the mouse myeloma cell SP2/0 expression system used in marketed cetuximab products. The safety and efficacy of CMAB009 have been confirmed from the results of two completed clinical trials on a total of 530 subjects, which were the largest clinical trials of anti-EGFR mAb developed in China by a local Chinese company. Based on our clinical trial results compared to published clinical trial results for currently marketed cetuximab products, CMAB009 significantly reduces immunogenicity and decreases the incidence of adverse reactions, such as severe hypersensitivity. We believe that CMAB009 is safer than, and as effective as, currently marketed cetuximab drugs for the treatment of mCRC.

Management Discussion and Analysis

During the Reporting Period, CMAB009 was under phase III clinical trials for colorectal cancer. The outbreak of the Pandemic, and the recent rebound of the Pandemic had certain impacts on our research and development in 2021. We expect to file the new drug marketing application with the NMPA in the third quarter of 2022 upon completion of clinical observation and data analysis of all cases. We are also preparing for clinical trials of other indications of CMAB009. Currently, we expect that CMAB009 may be approved by the NMPA for marketing in the third quarter of 2023.

Other Product Candidates

CMAB807 (Denosumab) is a human IgG2 monoclonal antibody with affinity and specificity for human RANKL (receptor activator of nuclear factor kappa-B ligand), which is a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. CMAB807 prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bones. CMAB807 is currently under phase III clinical trials for osteoporosis and we expect that CMAB807 will be approved by NMPA for marketing in the first quarter of 2024 for the indication of osteoporosis.

We have also developed a dosage form of CMAB807 for the treatment of tumor bone metastasis and conducted pre-clinical research, i.e. CMAB807X (denosumab). We expect that phase III clinical trials for tumor bone metastasis will be launched in the first quarter of 2023. It is currently expected that CMAB807X will be approved by NMPA for marketing in the first quarter of 2027 for the indication of tumor bone metastasis.

CMAB819 (nivolumab) is our biosimilar drug candidate currently undergoing phase I clinical trial. CMAB819 was approved by the NMPA for clinical trial in September 2017. As of June 30, 2021, we have commenced the phase I clinical trial. We expect that CMAB819 may be approved by the NMPA for marketing in the fourth quarter of 2027. CMAB819 is indicated for the treatment of metastatic non-small cell lung cancer, hepatocellular carcinoma and head and neck squamous cell carcinomas (HNSCC).

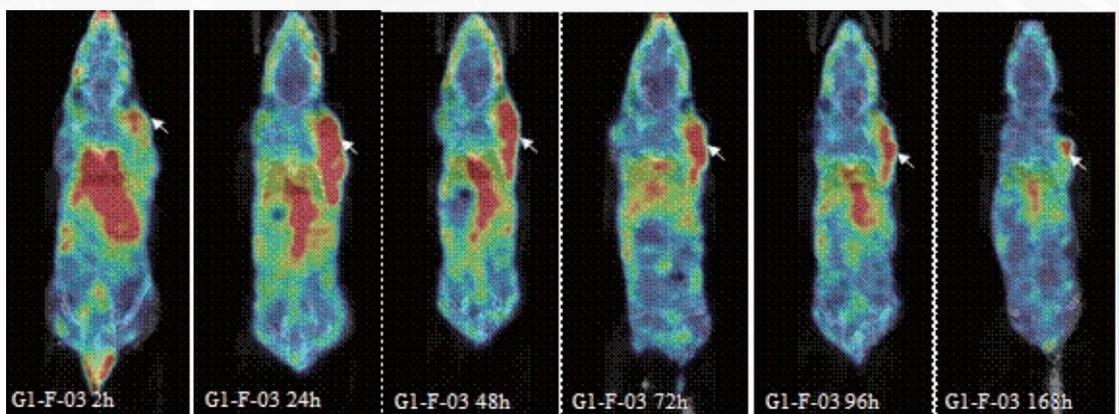
Management Discussion and Analysis

CMAB810 (pertuzumab) is our pre-clinical trial biosimilar drug candidate. The related screening processes, the establishment of a cell bank, and a lab-scale process for CMAB810 have been completed. We are carrying out preclinical animal experiments for CMAB810 and expect to apply for clinical trials in the fourth quarter of 2022. We expect that CMAB810 may be approved by the NMPA for marketing in the first quarter of 2028. CMAB810 is indicated for the treatment of breast cancer.

CMAB816 (canakinumab) is our pre-clinical trial biosimilar drug candidate. The related screening processes and the establishment of cell bank have been completed. It is expected to apply for clinical trials in the third quarter of 2022. We expect that CMAB816 may be approved by the NMPA for marketing in the second quarter of 2026. CMAB816 is indicated for the treatment of periodic fever syndrome and systemic juvenile idiopathic arthritis. Further, according to the latest research results, canakinumab can potentially reduce the incidence of lung cancer and lung cancer-related mortality rates.

CMAB017 is an innovative candidate in preclinical research stage and an innovative strong antibody drug. At present, the screening of high expression engineering cells and the establishment of engineering cell bank have been completed. The research on the production process and formulation selection has been concluded. Results of the completed experimental study on tissue distribution of tumor-bearing mice show that CMAB017 concentrates locally in tumor 24-72 hours after administration. We expect to commence phase III clinical trial in the fourth quarter of 2024. We expect that CMAB017 may be approved by the NMPA for marketing in the fourth quarter of 2027. Regarding CMAB017, the design of blocking peptide is expected to significantly reduce adverse skin reactions, gastrointestinal mucosa, etc. The selection of IgG1 constant region can enhance the effect mediated by Fc fragment of antibody and thus improve the curative effect. Based on the advantages of safety and curative effect, the cost of case medication is far lower than CMAB009, and it is expected that more new strong antibody drugs will be developed by leveraging the research and development platform of CMAB017. CMAB017 is indicated for the treatment of KRAS wild-type colorectal cancer.

Management Discussion and Analysis



CMAB015 is a biosimilar candidate for secukinumab, which is under preclinical study. At present, the screening of high expression engineering cells and the establishment of engineering cell bank have been completed. The research on production process is in progress and it is expected that we will apply for clinical trial in the first quarter of 2022. We expect that CMAB015 may be approved by the NMPA for marketing in the second quarter of 2026. CMAB015 targets interleukin 17A (IL-17A) for treating plaque psoriasis, psoriatic arthritis and ankylosing spondylitis.

CMAB018 is a biosimilar candidate for mepolizumab, which is under preclinical study. At present, the screening of high expression engineering cells and the establishment of engineering cell bank have been completed, the research on production process is in progress and it is expected that we will apply for clinical trial in the second quarter of 2022. We expect that CMAB018 may be approved by the NMPA for marketing in the fourth quarter of 2026. CMAB018 targets interleukin 5 (IL-5) in treating severe asthma and eosinophilic granulomatous polyangiitis.

CMAB022 is a candidate biosimilar product of stelara® (ustekinumab). Ustekinumab is a monoclonal antibody targeting interleukin-12 (IL-12) and interleukin-23 (IL-23). It inhibits these two proinflammatory cytokines by binding to the P40 subunit shared by IL-12 and IL-23 and preventing them from binding to the cell surface IL-12 receptor β 1. IL-12 and IL-23 are two natural proteins, which play a key role in immune-mediated inflammatory diseases, including plaque psoriasis, psoriatic arthritis and Crohn's disease, indications include: moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy; adults with active psoriatic arthritis (PsA); adults with active ankylosing spondylitis (AS); adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. The pilot processes are currently in development. We expect to apply for clinical trials in the fourth quarter of 2022 and CMAB022 may be approved by the NMPA for marketing in the first quarter of 2027.

Management Discussion and Analysis

Research and development of new drug candidates

We have launched a series of follow-up R&D on new antibody drugs for the treatment of autoimmune diseases and/or tumor diseases. We expect to successfully complete the screening of several new antibody drugs, cell banking and even start pre-clinical animal experiments, thus further expand our product line and provide sufficient drug candidate pipeline expansion for our long-term development.

Research and development system

We have developed efficient R&D capabilities, broad and advanced preparation technologies, and low-cost drug production capabilities that will allow us to offer high quality and affordable innovative biopharmaceutical products to patients in China and other emerging markets. Within our product pipeline, CMAB008 has been marketed and commercialized, CMAB007 has completed clinical trials and will apply to be marketed soon while CMAB009 and CMAB807 are under phase III clinical trials. We also own a number of patents for our core technologies, including antibody engineering and humanization technologies, efficient expression vector construction technologies, efficient clone screening technologies, as well as a proprietary R&D animal model. Our R&D activities are carried out by three core teams: basic R&D, clinical trials, and industrialized good manufacturing practices (“GMP”). The operations, design, and construction needs of these three core teams are supported by an assisting engineering team. Our R&D teams consist of professionals who have extensive industry experience in biologics R&D and have gained valuable work experience at global pharmaceutical companies. Employees in our R&D teams possess strong academic backgrounds from leading institutions in immunology, molecular biology, oncology or monoclonal antibody development.

Management Discussion and Analysis

DRUG CANDIDATES COMMERCIALIZATION AND PRODUCTION FACILITIES CONSTRUCTION

Existing production facilities

Our production site in Taizhou has two buildings of 30,000 square meters in total and houses our mAb production facilities. The two buildings are equipped with production facilities currently in operation, including (i) four $3 \times 1,500\text{L}$ antibody bioreactor systems and related purification lines, (ii) an injection vial filling line capable of manufacturing four million units per annum and (iii) a pre-filled syringes production line capable of manufacturing one million units per annum. Our production facilities have successfully passed the GMP compliance inspection for CMAB008 by the Jiangsu Provincial Drug Administration and have commenced commercial production.

Construction of new production facilities

We constructed new production facilities on a parcel of industrial land of approximately 100,746 square meters in the Taizhou Hi-tech Zone. Our expansion plan includes the construction of (i) large-scale monoclonal antibody drug substance production lines with scale of each cell reactor reaching 7,500L and 18,000L, respectively, and (ii) two drug product filling lines which have commenced construction and already completed the construction of the plant, design and purchase of key equipment and is expected to be put into trial operation in the middle of 2022.

Marketing and distribution

Further, during the rapid growth of the pharmaceutical market in China, the central procurement under the medical insurance that may be extended to cover biological drugs in the future and the increased effort in national negotiations on medical insurance will restructure the pharmaceutical market in China to a large extent. We will actively participate in the national medical reform with our advantages in advanced technology, quality and cost and capture the opportunities presented during the policy reform so as to capture the huge unmet market demand in China. At the same time, we have also initiated our global market expansion and accelerated the registration and launching of our drugs in the international market.

Management Discussion and Analysis

We are in the process of building our sales and marketing strategy. Our marketing strategies to focus on precision marketing through academic promotion and center around increasing knowledge and awareness of the clinical benefits of our pharmaceuticals among medical professionals. We intend to focus on hospitals with potential clinical demand for our products as our primary customer base. We intend to continue to communicate frequently with major hospitals in China to understand these hospitals and their doctors' academic views on antibody drugs and patient demands. We also intend to continue to meet industry experts regularly to understand industry trends. We will continue to participate in academic conferences, seminars and symposia, which include large-scale national and provincial conferences organized by the Chinese Medical Association or its local chapters, as well as smaller events tailored to specific cities and hospital departments to promote our brand awareness.

Half of our current core sales team members have over a decade of experience in sales and management of antibody drugs, including the first antibody drug produced by a local Chinese company marketed in China. Our sales team has maintained direct relationships with hospitals through their participation in and support of our clinical trials. In anticipation of the launch of our products, we have been expanding our sales and marketing force. In line with our sales and marketing strategy, we will focus on the recruitment of sales and marketing personnel who have notable academic profiles in medicine and pharmacy, and have over three years' clinical experience in therapeutic areas of cancers and autoimmune diseases. We expect to implement certain procedures to ensure that our academic promotion and general marketing efforts are in compliance with applicable laws and regulations.

We expect to sell our products to (i) distributors that sell our products to hospitals and (ii) direct-to-patient pharmacies and others. We are establishing our network of distributors for CMAB008 in accordance with the national drug sales regulations. Our distribution model is consistent with customary industry practice and serves to ensure efficient coverage of our sales network while controlling our cost of distribution and account receivables. We intend to select our distributors based on their qualifications, reputation, market coverage and sales experience. To distribute our products, a distributor must maintain its business license and other requisite licenses and permits. A distributor must also maintain extensive hospital coverage in the designated region. A distributor must be capable of delivering our products to covered hospitals in a safe and timely manner. We plan to actively monitor the inventory levels of our distributors to increase the efficiency of our distribution network.

Management Discussion and Analysis

Quality assurance

We believe that an effective quality management system for our raw materials, equipment and finished products is critical to ensure the quality of our services and maintain our reputation and success. To ensure that our products and services consistently meet high industry standards and requirements, we have also established a company-level quality assurance department to inspect the quality of our products and services. It is also responsible for the approval, organization and coordination of quality control and quality assurance procedures within each subsidiary. Facilities and equipment are subject to inspection measures such as united registrar systems, factory acceptance testing, site acceptance testing, installation qualification, operator qualification, performance qualification, and regular maintenance throughout their entire life cycles. Our manufacturing business lines are inspected in accordance with the PRC national laboratory quality control standard and the GMP management requirements; our research and development business lines are also inspected in accordance with the GMP management requirements.

FUTURE AND OUTLOOK

We leverage our efficient sales system with a focus on niche markets to capture the opportunities presented in the pharmaceutical reform in China.

Under the implementation of the new medical insurance policy in recent years, the pharmaceutical market in China is undergoing significant market restructuring. Companies with more competitive advantages in quality and pricing have benefited greatly from the negotiations on medical insurance price between the National Healthcare Security Administration and regional healthcare security administrative bodies at all levels and negotiations in relation to central procurement for drugs covered under the medical insurance. As a result, the overall market penetration has increased significantly during the reformation. This trend will drive the development of the pharmaceutical market in China for a long time into the future. Riding on the trend of the overall pharmaceutical policy reform, we will build a sales team in China with high efficiency and academic promotion as its core strategy, focusing on niche markets, such as gastroenterology, respiratory, rheumatology and oncology, with an aim to promote our products and cultivate the practice of antibody drugs application. We will actively monitor, and participate in, the negotiations of medical insurance, especially focusing on capturing the huge potentials brought by the negotiations of central procurement for biological products under the medical insurance. Relying on the significant advantages of our drugs in terms of quality and cost, we will capture opportunities presented in the significant increase in market penetration caused by the policy reform, effectively satisfying the unmet market demand in China in respect of biological agents with high quality products and ultimately benefiting patients.

Management Discussion and Analysis

The antibody drugs development in overseas markets has shown a rapid increase resulting in a huge unmet global market demand for antibody drugs, especially for those with The Pharmaceutical Inspection Co-operation Scheme (PIC/S) as the core. In light of the policy reform in China, the economies of scale of antibody drugs will greatly enhance the global competitiveness of Chinese antibody drugs. In view of this, we will work closely with our overseas market expansion partners to initiate new drug registration and launching new drugs in different countries and regions in a comprehensive and flexible manner with multiple products, with an aim to promote our products' global presence and accelerate their growth in the global market.

Continue to advance the clinical research and commercialization of our drug candidates

Over the short-term, we intend to focus on completing clinical trials and the eventual commercialization of our current pipeline of drug candidates, particularly CMAB008, CMAB007, CMAB009 and CMAB807. To bring our products to market, we aim to reinforce our R&D teams, particularly the clinical medicine team, through the provision of regular professional training and pushing ahead with the clinical trials for product candidates. We are also in the process of establishing a sales team consisting of staff with strong academic promotion experience and capabilities. Our goal is to generate stable revenue and profits in the future by creating our own sales team in China and strengthening our commercialization capabilities by further building our sales team.

Continue to maintain investments in advanced technologies and product development

We believe R&D is the key element to support our future growth and our ability to maintain our competitiveness in a global biopharmaceutical market. We plan to upgrade the development of our integrated technological platforms from molecular design to commercialized production, and focus on the R&D of biologics with huge clinical demand and the potential for sustained and rapid growth in China. In order to capture new opportunities in the biopharmaceutical market, we plan to continue increasing our investment in innovative technologies for the development of drugs with improved curative effects and less toxic side effects in order to maintain our industry leading position. We also expect to invest in talent to expand and enhance our R&D team.

Management Discussion and Analysis

Continue to attract and nurture high quality talent to support our rapid growth

Recruiting and retaining high quality scientific and technological talent as well as other leaders in R&D technology will be key to our success. We plan to leverage our close cooperation with elite universities in China and internationally to recruit and develop outstanding R&D personnel. We also plan to provide systematic and sophisticated training and development programs to our research teams in order to enhance and optimize their scientific and technical abilities to benefit our Company. Part of this strategy involves the creation of an incentive scheme to retain and motivate high-performing team members.

Establish global brand awareness and foster deeper and more extensive cooperative relationship with domestic and overseas renowned pharmaceutical companies

To build our brand internationally and to support our sustainable growth, we plan to in-license products from global pharmaceutical companies for sales in China and/or to transfer or out-license overseas product rights of certain of our drug candidates to other pharmaceutical companies. We have established collaborative partnerships with domestic and foreign pharmaceutical companies with overseas channel resources, and constantly seek more opportunities to cooperate with potential partners with sales resources, in order to enter and expand our market share in markets outside of China and to further broaden the geographic coverage of our business. As part of this strategy, we may take advantage of strategic opportunities for mergers and acquisitions internationally to expand our pipeline of products for R&D development and sales in overseas markets.

FINANCIAL INFORMATION

The financial information set out below in this report represents an extract from the interim condensed consolidated financial information, which is unaudited but has been reviewed by the Audit Committee.

Management Discussion and Analysis

FINANCIAL REVIEW

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

	For the six months ended June 30,			
	2021 <i>RMB'000</i> (unaudited)	2020 <i>RMB'000</i> (unaudited)	Change <i>RMB'000</i> (unaudited)	Change (%) (unaudited)
Revenue	81,246	–	81,246	–
Cost of sales	(16,769)	–	(16,769)	–
Gross profit	64,477	–	64,477	–
Other income	3,558	20,939	(17,381)	(83.0)
Other gains and losses	(4,719)	19,066	(23,785)	(124.8)
Research and development expenses	(163,455)	(60,828)	(102,627)	168.7
Administrative expenses	(43,755)	(30,741)	(13,014)	42.3
Finance costs	(1,267)	(2,624)	1,357	(51.7)
Loss before tax	(145,161)	(54,188)	(90,973)	167.9
Income tax expense	–	–	–	–
Loss and total comprehensive expense for the period	(145,161)	(54,188)	(90,973)	167.9
Attributable to:				
Owners of the Company	(145,161)	(54,188)	(90,973)	167.9
Loss per share attributable to ordinary equity holders of the Company				
– Basic	RMB(0.04)	RMB(0.01)		
– Diluted	RMB(0.04)	RMB(0.01)		

Management Discussion and Analysis

Revenue

The Group's revenue increased from RMB0.0 million for the six months ended June 30, 2020 to RMB81.2 million for the six months ended June 30, 2021, primarily attributable to the intellectual property transfer agreement on CMAB806 during the Reporting Period. Set out below are the components of revenue for the periods indicated:

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Revenue from intellectual property transfer agreement on CMAB806 – at a point in time	81,246	–

Cost of sales

The Group's cost of sales increased from RMB0.0 million for the six months ended June 30, 2020 to RMB16.8 million for the six months ended June 30, 2021, primarily attributable to the cost corresponding to the revenue from intellectual property transfer agreement on CMAB806 recognized during the Reporting Period. Set out below are the components of cost of sales for the periods indicated:

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Cost of sales corresponding to revenue from intellectual property transfer agreement on CMAB806	16,769	–

Management Discussion and Analysis

OTHER INCOME

Other income of the Group decreased by 83.0% from RMB20.9 million for the six months ended June 30, 2020 to RMB3.6 million for the six months ended June 30, 2021, which was primarily due to a decline in interest income due to decreased monetary funds, which is caused by the increase of R&D investment and a drop in government subsidies from the corresponding period of last year during the Reporting Period. Set out below are the components of other income for the periods indicated:

	For the six months ended June 30,	
	2021 RMB'000 (unaudited)	2020 RMB'000 (unaudited)
Bank interest income	1,043	8,173
Government grants and subsidies related to income	2,515	12,766
	3,558	20,939

OTHER GAINS AND LOSSES

Other gains and losses of the Group decreased by 124.8% from gains of RMB19.1 million for the six months ended June 30, 2020 to losses of RMB4.7 million for the six months ended June 30, 2021, which was primarily due to a significant decrease in exchange rate of foreign currencies held by the Group.

Set out below are the components of other gains and losses for the periods indicated:

	For the six months ended June 30,	
	2021 RMB'000 (unaudited)	2020 RMB'000 (unaudited)
Net foreign exchange (losses)/gains	(4,646)	13,677
Others	(73)	5,389
	(4,719)	19,066

Management Discussion and Analysis

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses of pipelines of the Group increased by 168.7% from RMB60.8 million for the six months ended June 30, 2020 to RMB163.5 million for the six months ended June 30, 2021, primarily due to intellectual property license-in expenses of RMB66.0 million incurred for the acquisition of CMAB807 during the Reporting Period.

The Group's research and development expenses mainly include contract costs, raw materials and consumables, staff cost, depreciation and amortization, intellectual property license-in expenses and others.

Set out below are the components of research and development expenses for the periods indicated:

	For the six months ended June 30,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
	(unaudited)	(unaudited)
Contract costs	51,999	25,609
Raw materials and consumables	13,090	11,193
Staff cost	24,235	17,174
Depreciation and amortization	3,895	3,770
Intellectual property license-in expenses	66,038	–
Others	4,198	3,082
Total	163,455	60,828

Management Discussion and Analysis

ADMINISTRATIVE EXPENSES

Administrative expenses of the Group increased by 42.3% from RMB30.7 million for the six months ended June 30, 2020 to RMB43.8 million for the six months ended June 30, 2021, primarily due to an increase in depreciation from new production plants that have been constructed.

Administrative expenses of the Group primarily comprise of staff salary and benefit costs of our non-R&D personnel, depreciation and others.

Set out below are the components of administrative expenses for the periods indicated:

	For the six months ended June 30,	
	2021	2020
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Staff cost	19,414	16,065
Depreciation	14,190	7,366
Others	10,151	7,310
Total	43,755	30,741

FINANCE COSTS

Finance costs of the Group decreased by 51.7% from RMB2.6 million for the six months ended June 30, 2020 to RMB1.3 million for the six months ended June 30, 2021, which was primarily due to no outstanding loans during the Reporting Period.

The Group's finance costs mainly include interests on bank loans and lease liabilities.

Management Discussion and Analysis

LIQUIDITY AND CAPITAL RESOURCES

Our trade receivables increased from RMB0.0 million as at December 31, 2020 to RMB11.5 million as at June 30, 2021, which was primarily due to the outstanding balance of the intellectual property transfer agreement on CMAB806 during the Reporting Period.

Set out below is an analysis of the liquidity and capital resources at the dates indicated:

	At June 30, 2021 RMB'000 (unaudited)	At December 31, 2020 RMB'000 (audited)	Change (%) (unaudited)
Trade receivables	11,468	–	–
Prepayments and other receivables	38,391	31,673	21.2
Inventories	37,664	33,427	12.7
Contract costs	850	16,769	(94.9)
Pledged bank deposits	2,000	2,000	0.0
Rental deposit to a related party	411	411	0.0
Cash and bank balances	307,178	484,846	(36.6)
Total	397,962	569,126	(30.1)

INDEBTEDNESS

As of June 30, 2021, we had non-trade amount due to a related party of RMB2.8 million and lease liabilities of RMB37.5 million. As of the same date, none of our existing indebtedness included any material covenants or covenants that could potentially limit our ability to incur new indebtedness.

Management Discussion and Analysis

Set out below is a breakdown of our outstanding non-trade amount due to a related party and lease liabilities at the dates indicated:

	At June 30, 2021 RMB'000 (unaudited)	At December 31, 2020 RMB'000 (audited)
Unsecured and unguaranteed amount due to Biomabs	2,762	21
Lease liabilities	37,498	40,348

As at June 30, 2021, we, as a lessee, had outstanding lease liabilities for the remaining terms of relevant lease agreements in an aggregate amount of RMB37.5 million.

As at June 30, 2021, we did not have any outstanding debt securities, charges, mortgages, or other similar indebtedness, hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are guaranteed, unguaranteed, secured or unsecured, any guarantees or other material contingent liabilities.

CAPITAL STRUCTURE

On May 31, 2019, 783,580,000 Shares were issued under the Global Offering and the Shares were listed on the Main Board of the Stock Exchange. There were no changes in the capital structure of the Group since then. The share capital of the Group only comprises ordinary Shares. As at June 30, 2021, the total issued share capital of the Company was US\$412,408 divided into 4,124,080,000 Shares.

Management Discussion and Analysis

The capital structure of the Group was 24.1% debt and 75.9% equity as at June 30, 2021, compared with 24.2% debt and 75.8% equity as at December 31, 2020.

FOREIGN EXCHANGE

Foreign currency risk refers to the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which our Group conducts business may affect our financial condition and results of operation. The Group mainly operates in the PRC and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to Hong Kong dollars and the U.S. dollars. The conversion of foreign currencies into RMB, including Hong Kong dollars and the U.S. dollars, has been based on rates set by the People's Bank of China. The Group primarily limits our exposure to foreign currency risk by closely monitoring the foreign exchange market. During the Reporting Period, the Group did not enter into any currency hedging transactions.

GEARING RATIO

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at June 30, 2021 the gearing ratio of the Group was 24.1% (unaudited) (as at December 31, 2020: 24.2% (audited)).

The following table sets forth our other key financial ratios as of the dates indicated.

	At June 30, 2021 (unaudited)	At December 31, 2020 (audited)
Current ratio ⁽¹⁾	2.1	2.8
Quick ratio ⁽²⁾	1.9	2.6

Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

Our current ratio decreased from 2.8 as of December 31, 2020 to 2.1 as of June 30, 2021, and our quick ratio decreased from 2.6 as of December 31, 2020 to 1.9 as of June 30, 2021, primarily due to utilization of monetary funds for operation as scheduled.

Other Information

INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2021.

USE OF NET PROCEEDS FROM LISTING

With the Shares of the Company listed on the Stock Exchange on May 31, 2019, the net proceeds from the Global Offering (after deducting the underwriting fees and related expenses) were approximately HK\$1,144.5 million (equivalent to approximately RMB1,005.1 million), which included approximately RMB37.7 million which forms part of the Listing expenses payable settled after receipt of the proceeds from the Listing. By excluding this portion, the net proceeds planned for applications amount to approximately RMB967.4 million. As of June 30, 2021, the Company used a total of approximately RMB658.2 million of the proceeds, including approximately RMB163.0 million for research and development of our Core Products, approximately RMB307.3 million for production scale-up and construction of new production facilities in Taizhou, PRC, approximately RMB116.9 million for research and development of our other candidate products, approximately RMB51.0 million for working capital and other general corporate purposes and approximately RMB20.0 million for acquisition of CMAB807 license. The Company intends to apply such net proceeds in accordance with the plan as set out in the Prospectus and the announcement published by the Company on March 1, 2021. The table below sets out the planned applications of the net proceeds of the Global Offering and actual usage up to June 30, 2021^{(1) (2)}:

Use of proceeds	Original Allocation of the proceeds (RMB million)	Revised allocation of the proceeds ⁽³⁾ (RMB million)	Utilized amount (as of June 30, 2021) (RMB million)	Unutilized amount (as of June 30, 2021) (RMB million)	Expected timeline for fully utilizing the unutilized amount
For R&D of our Core Products	180.9	180.9	163.0	17.9 ⁽⁴⁾	By June 30, 2022
For production scale-up and construction of new production facilities in Taizhou, PRC	497.2	497.2	307.3	189.9 ⁽⁵⁾	By December 31, 2022
For R&D of our other product candidates	194.5	194.5	116.9	77.6 ⁽⁶⁾	By June 30, 2022
For working capital and other general corporate purposes	94.8	74.8	51.0	23.8	By December 31, 2021
For acquisition of CMAB807 License	0.0	20.0	20.0	-	
Total	967.4	967.4	658.2	309.2	

Other Information

Note:

- (1) Net IPO proceeds were received in Hong Kong dollar and translated to Renminbi for application planning.
- (2) Timetable for utilizing the unutilized proceeds as disclosed above was prepared based on the best estimates of the Board and the latest information as of the date of this interim report.
- (3) On March 1, 2021, the Board resolved to allocate approximately RMB20 million of the proceeds raised from the global offering of the Company originally allocated for working capital and other general corporate purposes to finance part of the consideration for acquisition of CMAB807 License.
- (4) The application for new drug marketing of CMAB008 has been approved in July 2021, CMAB007 has completed phase III clinical trials and CMAB009 are currently under phase III clinical trials.
- (5) We are constructing new production facilities in the second building of our Taizhou production site and on the parcel of industrial land of approximately 100,746 square meters in Taizhou Hi-tech Zone.
- (6) Of our other drug candidates, CMAB807 is currently undergoing phase III clinical trials and CMAB819 is currently undergoing phase I clinical trials.

SIGNIFICANT INVESTMENTS, MATERIAL ACQUISITIONS AND DISPOSALS

Save as disclosed in this interim report, as at the date of this interim report, there were no significant investments held by the Group or future plans regarding significant investment or capital assets. For the six months ended June 30, 2021, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

EMPLOYEE AND REMUNERATION POLICY

As of June 30, 2021, we had a total of 405 employees, of which 91 are located in Shanghai and 314 are located in Taizhou. The table below sets forth a breakdown of our employees by function:

Function	Number of Employees
Business units	58
R&D personnel ⁽¹⁾	233
Sales and marketing ⁽²⁾	40
Administration	27
Management	47
Total	405

Notes:

- (1) The number of R&D personnel here excludes 22 R&D team members who have been included in our management.
- (2) The number of sales and marketing personnel here excludes our seven core sales and marketing team members, who have been included in our management.

Our success depends on our ability to attract, recruit and retain qualified employees. We provide our employees with opportunities to work on cutting-edge biologics projects with world-class scientists. We aim to attract qualified employees with overseas educational backgrounds and relevant experience gained from global pharmaceutical or biotechnology companies. As of June 30, 2021, we had 127, 17 and 7 scientists holding a bachelor's degree or equivalent, a master's degree or equivalent, and a Ph.D. degree or equivalent in fields that are highly relevant to our business. In addition, as of the same date, 151 out of our 255 R&D personnel (including those who are our management) held a bachelor's degree or above.

Our employment agreements typically cover matters such as wages, benefits and grounds for termination. The remuneration package of our employees generally includes salary and bonus elements. In general, we determine the remuneration package based on the qualifications, position and performance of our employees. We also make contributions to the social insurance fund, including basic pension insurance, medical insurance, unemployment insurance, childbirth insurance, work-related injury insurance funds, and housing reserve fund. In addition, we have adopted an employee share option plan to provide an additional means to attract, motivate, retain and reward our employees.

We have established a labor union at Taizhou that represents employees with respect to the promulgation of bylaws and internal protocols. As of June 30, 2021, all of our employees at Taizhou were members of the labor union. We believe that we maintain a good working relationship with our employees. We had not experienced any material difficulty in recruiting employees for our operations during the Reporting Period and up to the date of this report.

Other Information

INTERESTS AND SHORT POSITIONS OF THE DIRECTORS AND THE CHIEF EXECUTIVE OF THE COMPANY IN THE SHARES, UNDERLYING SHARES AND DEBENTURES OF THE COMPANY AND ITS ASSOCIATED CORPORATIONS

As at June 30, 2021, the interests or short positions of our Directors and chief executives in the Shares, underlying shares and debentures of the Company or its associated corporations (within the meaning of Part XV of the Securities and Futures Ordinance (the "SFO")) which were required to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests or short positions which they were taken or deemed to have under such provisions of the SFO), or (ii) to be entered into the register required to be kept by the Company pursuant to Section 352 of the SFO, or (iii) as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code of Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules were as follows:

Name of Director	Nature of interest	Number of Shares or underlying Shares	Approximate percentage of shareholding interest ⁽¹⁾
Mr. Guo Jianjun (郭建軍)	Interest in controlled corporation (L) ⁽²⁾	2,227,000,000	54.00%
Dr. Wang Hao (王皓)	Beneficial owner (L) ⁽³⁾	24,827,006	0.60%
Mr. Li Yunfeng (李雲峰)	Beneficial owner (L) ⁽³⁾	3,236,234	0.08%
Dr. Li Jing (李晶)	Beneficial owner (L) ⁽³⁾	3,236,234	0.08%
Tao Jing (陶靜)	Beneficial owner (L) ⁽³⁾	3,236,234	0.08%
	Interest of Spouse (L) ⁽³⁾	75,192	0.002%

Notes:

- (1) As at June 30, 2021, the total number of issued shares of the Company was 4,124,080,000 Shares.
- (2) The Company is held as to 49.95% and 4.05% by Asia Mabtech and United Circuit, respectively. United Circuit is held as to 100% by Asia Mabtech, which is wholly-owned by Asia Pacific Immunotech Venture which is in turn wholly-owned by the Guo Family Trust, of which Mr. Guo Jianjun is the settlor. As such, Mr. Guo Jianjun is deemed or is taken to be interested in 167,025,000 Shares beneficially owned by United Circuit and 2,059,975,000 Shares beneficially owned by Asia Mabtech for the purpose of Part XV of the SFO.
- (3) These interests represented the share options granted under the Pre-IPO Share Option Scheme. For details, please refer to note 19 of the interim condensed consolidated financial information of this interim report.

Save as disclosed above, as at the date of this interim report, so far as the Directors and the chief executive of the Company are aware, none of the Directors or the chief executive of the Company had registered an interest or short position in any Shares or underlying Shares or debentures of the Company or its associated corporations (within the meaning of Part XV of the SFO) that was required to be notified under Division 7 and 8 of Part XV of the SFO or recorded pursuant to Section 352 of the SFO, or as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code.

SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES

As at June 30, 2021, the interests of relevant persons (other than a Director or the chief executive of the Company) who had interests or short positions in the Shares or the underlying shares, as recorded in the register required to be kept under Section 336 of SFO, were as follows:

Name of Shareholder	Nature of interest	Number of Shares	Approximate percentage of shareholding interest
Asia Mabtech ⁽¹⁾	Beneficial owner (L); Interest in controlled corporation (L)	2,227,000,000	54.00%
United Circuit ⁽¹⁾	Beneficial owner (L)	167,025,000	4.05%
Guo Family Trustee ⁽¹⁾	Interest in controlled corporation (L)	2,227,000,000	54.00%
Asia Pacific Immunotech Venture Limited ⁽¹⁾	Interest in controlled corporation (L)	2,227,000,000	54.00%
Mr. Guo Jianjun ⁽¹⁾	Interest in controlled corporation (L)	2,227,000,000	54.00%

Other Information

Name of Shareholder	Nature of interest	Number of Shares	Approximate percentage of shareholding interest
CDH PE ⁽²⁾	Beneficial owner (L)	742,348,180	18.00%
CDH Fund V, L.P. ("CDH Fund") ⁽²⁾	Interest in controlled corporation (L)	742,348,180	18.00%
CDH V Holdings Company Limited ("CDH V") ⁽²⁾	Interest in controlled corporation (L)	742,348,180	18.00%
China Diamond Holdings V Limited ("CDH Diamond V") ⁽²⁾	Interest in controlled corporation (L)	742,348,180	18.00%
China Diamond Holdings Company Limited ("China Diamond") ⁽²⁾	Interest in controlled corporation (L)	742,348,180	18.00%
FH Investment ⁽³⁾	Beneficial owner (L)	213,435,680	5.18%
Link Best Capital Limited ⁽³⁾	Interest in controlled corporation (L)	213,435,680	5.18%

Notes:

- (1) The Company is held as to 49.95% and 4.05% by Asia Mabtech and United Circuit, respectively. United Circuit is held as to 100% by Asia Mabtech, which is wholly-owned by Asia Pacific Immunotech Venture which is in turn wholly-owned by the Guo Family Trust, of which Mr. Guo Jianjun is the settlor and Guo Family Trustee is the trustee. As such, Mr. Guo Jianjun is deemed or is taken to be interested in 167,025,000 Shares beneficially owned by United Circuit and 2,059,975,000 Shares beneficially owned by Asia Mabtech for the purpose of Part XV of the SFO.
- (2) The Company is held as to 18.00% by CDH PE. CDH PE is wholly-owned by CDH Fund. Pursuant to the SFO, CDH Fund is therefore deemed to be interested in the shares held by CDH PE. CDH Fund is controlled by CDH V, which in turn held as to 80% by China Diamond V. China Diamond V is in held as to 100% by China Diamond which is held by independent third parties.
- (3) FH Investment is a direct wholly-owned subsidiary of Link Best Capital Limited, which is held by independent third parties.

Saved as disclosed above, so far as the Directors are aware, no other persons had registered an interest or short position in any Shares or underlying shares or debentures of the Company that was required to be recorded pursuant to Section 336 of the SFO, or as otherwise notified.

PRE-IPO SHARE OPTION SCHEME

Save as disclosed below and in note 19 of the interim condensed consolidated financial information of this interim report, the Company did not have other share option schemes.

The Company adopted the Pre-IPO Share Option Scheme on August 10, 2018. On August 18, 2018, the Company granted an aggregate of 83,512,500 share options to 62 grantees, representing the rights to subscribe for 83,512,500 Shares (taking into account the Capitalization Issue). Subsequent to the granting of the share options, a total of twelve of the grantees resigned from their respective positions within our Group. As such, the share options held by these twelve grantees were lapsed and no longer exercisable. As of June 30, 2021, the number of Shares underlying the outstanding and unexercised share options granted under the Pre-IPO Share Option Scheme amounted to 79,946,645 Shares and 1.94% of the issued share capital of the Company as at the date of this interim report. None of the share options granted under the scheme has been exercised by any grantee.

Details of the movements of the options granted under the Pre-IPO Share Option Scheme during the Reporting Period are as follows:

Category	Grant Date	Outstanding at January 1, 2020	Number of Share Options During the Reporting Period			Outstanding at June 30, 2021
			Granted	Exercised	Forfeited	
Category 1:						
Directors						
Dr. Wang Hao	August 18, 2018	24,827,006	-	-	-	24,827,006
Mr. Li Yunfeng	August 18, 2018	3,236,234	-	-	-	3,236,234
Dr. Li Jing	August 18, 2018	3,236,234	-	-	-	3,236,234
Mr. Tao Jing	August 18, 2018	3,236,234	-	-	-	3,236,234
	Sub-total	34,535,708	-	-	-	34,535,708
Category 2:						
Employees						
	August 18, 2018	45,511,193	-	-	(100,256)	45,410,937
	Total	80,046,901	-	-	(100,256)	79,946,645

For further details, please refer to note 19 of the interim condensed consolidated financial information of this interim report.

Other Information

COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Group is committed to maintaining high standard of corporate governance to safeguard the interests of the Shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability.

The Company's corporate governance practices are based on the principles and code provisions as set out in the CG Code contained in Appendix 14 to the Listing Rules and the Company has adopted the CG code as its own code of corporate governance. The CG Code has been effective and applicable to the Company with effect from the Listing Date. The Board is of the view that the Company has complied with the applicable code provisions as set out in the CG Code during the six months ended June 30, 2021. The Board will periodically review and enhance its corporate governance practices to ensure that the Company continues to meet the requirements of the CG Code.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS

With consent from the Directors, 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 (the "**Model Code**") as the guidelines for the Directors' dealings in the securities of the Company since the Listing Date. Specific enquiry has been made to each Director and all Directors have confirmed that they have complied with the applicable standards set out in the Model Code during the six months ended June 30, 2021.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

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

AUDIT COMMITTEE AND REVIEW OF FINANCIAL REPORT

The independent auditors of the Company, namely Ernst & Young, have carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagement 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants.

The Audit Committee has examined the efficiency of our risk management and internal control system and is convinced that our internal control system is sufficient to identify, manage and reduce various risks arising from our business activities. The Audit Committee consists of two independent non-executive Directors, being Dr. Liu Linqing and Mr. Guo Liangzhong, and one non-executive Director, being Mr. Jiao Shuge. Dr. Liu Linqing serves as chairman of the Audit Committee.

The Audit Committee has reviewed the interim consolidated financial statements of the Group for the six months ended June 30, 2021. The Audit Committee has also discussed matters with respect to the accounting principles and policies adopted by the Company and internal control with members of senior management and the external auditors of the Company, Ernst & Young.

CHANGE IN INFORMATION OF DIRECTORS

As of June 30, 2021, there was no change in information of Directors subject to disclosure under Rule 13.51B(1) of the Listing Rules.

CONTINUING DISCLOSURE OBLIGATIONS PURSUANT TO THE LISTING RULES

Our Directors have confirmed that as at June 30, 2021, there were no circumstances that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

Other Information

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

In July 2021, the new drug application (NDA) of CMAB008 類停® (infliximab for injection), a core product of the Company and a recombinant anti-tumor necrosis factor- α human-mouse chimeric monoclonal antibody independently developed by the Company, was approved by the National Medical Products Administration of the People's Republic of China for the treatment of (i) ulcerative colitis in adults; (ii) ankylosing spondylitis; (iii) rheumatoid arthritis; (iv) Crohn's disease in adults and pediatric patients aged above 6 years old; (v) fistula Crohn's disease; and (vi) psoriasis. Please refer to the announcement of the Company published on July 14, 2021 for details of the aforementioned approval.

Save as disclosed in this interim report and above, there was no significant event subject to disclosure from June 30, 2021 to the date of this interim report.

APPRECIATION

On behalf of the Board, we wish to express our sincere gratitude to our Shareholders and business partners for their continued support, and to our employees for their dedication and hard work.

By Order of the Board
Mabpharm Limited
Jiao Shuge
Chairman

Hong Kong, August 27, 2021

Independent Review Report



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To the board of directors of Mabpharm Limited
(Incorporated in the Cayman Islands with limited liability)

INTRODUCTION

We have reviewed the interim financial information set out on pages 41 to 63, which comprises the condensed consolidated statement of financial position of Mabpharm Limited (the “**Company**”) and its subsidiaries (the “**Group**”) as at 30 June 2021 and the related condensed consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the six-month period then ended, and explanatory notes. The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited require the preparation of a report on interim financial information to be in compliance with the relevant provisions thereof and International Accounting Standard 34 *Interim Financial Reporting* (“**IAS 34**”) issued by the International Accounting Standards Board. The directors of the Company are responsible for the preparation and presentation of this interim financial information in accordance with IAS 34. Our responsibility is to express a conclusion on this interim financial information based on our review. Our report is made solely to you, as a body, in accordance with our agreed terms of engagement, and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

SCOPE OF REVIEW

We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the Hong Kong Institute of Certified Public Accountants. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Independent Review Report

CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the interim financial information is not prepared, in all material respects, in accordance with IAS 34.

Ernst & Young

Certified Public Accountants

Hong Kong

27 August 2021

Interim Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the six months ended 30 June 2021

	Notes	2021 (Unaudited) RMB'000	2020 (Unaudited) RMB'000
Revenue	5	81,246	–
Cost of sales	5	(16,769)	–
Gross profit		64,477	–
Other income	6	3,558	20,939
Other gains and losses	7	(4,719)	19,066
Research and development expenses		(163,455)	(60,828)
Administrative expenses		(43,755)	(30,741)
Finance costs	8	(1,267)	(2,624)
Loss before tax	9	(145,161)	(54,188)
Income tax expense	10	–	–
Loss and total comprehensive expense for the period		(145,161)	(54,188)
Attributable to: Owners of the Company		(145,161)	(54,188)
Loss per share attributable to ordinary equity holders of the Company	12		
– Basic		RMB (0.04)	RMB (0.01)
– Diluted		RMB (0.04)	RMB (0.01)

Interim Condensed Consolidated Statement of Financial Position

30 June 2021

	<i>Notes</i>	30 June 2021 (Unaudited) RMB'000	31 December 2020 (Audited) RMB'000
Non-current assets			
Plant and equipment	13	406,386	438,408
Right-of-use assets		69,640	74,209
Other non-current assets	14	104,637	81,294
Total non-current assets		580,663	593,911
Current assets			
Trade receivables	15	11,468	–
Prepayments and other receivables	16	38,391	31,673
Inventories		37,664	33,427
Contract costs	5	850	16,769
Pledged bank deposits	17	2,000	2,000
Rental deposit to a related party	21	411	411
Cash and bank balances	17	307,178	484,846
Total current assets		397,962	569,126
Current liabilities			
Trade and other payables	18	105,985	113,297
Amount due to a related party	21	50,039	75
Lease liabilities to third parties		4,612	4,146
Lease liabilities to a related party	21	2,985	4,386
Contract liabilities		16,144	70,058
Deferred income		12,065	10,665
Total current liabilities		191,830	202,627
Net Current Assets		206,132	366,499
Total Assets Less Current Liabilities		786,795	960,410

Interim Condensed Consolidated Statement of Financial Position

30 June 2021

<i>Notes</i>	30 June 2021 (Unaudited) RMB'000	31 December 2020 (Audited) RMB'000
Non-current liabilities		
Deferred income	14,000	47,109
Lease liabilities to third parties	29,901	31,816
Total non-current liabilities	43,901	78,925
Net Assets	742,894	881,485
Capital and reserves		
Share capital	2,804	2,804
Reserves	740,090	878,681
Total Equity	742,894	881,485

Interim Condensed Consolidated Statement of Changes in Equity

For the six months ended 30 June 2021

	Share capital RMB'000	Share premium RMB'000	Other reserve RMB'000	Share-option reserve RMB'000	Accumulated losses RMB'000	Total equity RMB'000
At 1 January 2021 (Audited)	2,804	1,400,504	(32,763)	31,695	(520,755)	881,485
Loss and total comprehensive expense for the period (Unaudited)	-	-	-	-	(145,161)	(145,161)
Recognition of equity-settled share-based compensation (Unaudited)	-	-	-	6,570	-	6,570
At 30 June 2021 (Unaudited)	2,804	1,400,504	(32,763)	38,265	(665,916)	742,894
At 1 January 2020 (Audited)	2,804	1,400,504	(32,763)	19,289	(336,123)	1,053,711
Loss and total comprehensive expense for the period (Unaudited)	-	-	-	-	(54,188)	(54,188)
Recognition of equity-settled share-based compensation (Unaudited)	-	-	-	6,872	-	6,872
At 30 June 2020 (Unaudited)	2,804	1,400,504	(32,763)	26,161	(390,311)	1,006,395

Interim Condensed Consolidated Statement of Cash Flows

For the six months ended 30 June 2021

	<i>Notes</i>	2021 (Unaudited) RMB'000	2020 (Unaudited) RMB'000
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax		(145,161)	(54,188)
Adjustments for:			
Bank interest income	6	(1,043)	(8,173)
Finance costs	8	1,267	2,624
Depreciation of plant and equipment	9	14,085	7,746
Depreciation of right-of-use assets	9	4,569	3,937
Loss on disposal of plant and equipment	9	73	–
Net foreign exchange losses/(gains)	7	4,646	(13,677)
Share-based payment expenses	9	6,570	6,872
		(114,994)	(54,859)
Increase in inventories		(4,237)	(4,525)
Decrease/(Increase) in contract costs		15,919	(2,928)
Increase in trade receivables		(11,468)	–
Increase in prepayments and other receivables		(6,718)	(19,090)
Decrease/(Increase) in other non-current assets		2,794	(3,472)
Increase in amount due to a related party		50,347	1,231
Increase/(Decrease) in trade and other payables		12,494	(12,991)
(Decrease)/Increase in contract liabilities		(53,914)	11,396
Increase in deferred income		1,400	150
Net cash flows used in operating activities		(108,377)	(85,088)
CASH FLOWS FROM INVESTING ACTIVITIES			
Interest received from bank		1,043	6,038
Purchase of plant and equipment		(61,230)	(92,865)
Disposal of plant and equipment		42	–
Placement of a time deposit		–	(45,012)
Withdraw of a time deposit		–	179,220
Withdraw of pledged bank deposits		–	153,008
Net cash flows (used in)/from investing activities		(60,145)	200,389

Interim Condensed Consolidated Statement of Cash Flows

For the six months ended 30 June 2021

	2021 (Unaudited) RMB'000	2020 (Unaudited) RMB'000
CASH FLOWS FROM FINANCING ACTIVITIES		
Interest paid	(1,294)	(2,832)
Issue costs paid	–	(1,280)
Repayment of bank loans	–	(63,086)
Repayments to a related party	(383)	(3,129)
Repayments of principal portion of lease liabilities	(2,809)	(3,331)
Net cash flows used in financing activities	(4,486)	(73,658)
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS		
Cash and cash equivalents at beginning of period	484,846	588,720
Effects of foreign exchange rate changes, net	(4,660)	12,982
CASH AND CASH EQUIVALENTS AT END OF PERIOD	307,178	643,345

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

1. GENERAL INFORMATION

Mabpharm Limited (the “**Company**”) was incorporated in the Cayman Islands as an exempted company with limited liability on 1 June 2018, and its shares are listed on The Stock Exchange of Hong Kong Limited on 31 May 2019. The address of the registered office is 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands and the principal place of business is located at Block G79, Lujia Road East, Koutai Road West, China Medical City, Taizhou, the People’s Republic of China (the “**PRC**”).

The Company is an investment holding company. The Company and its subsidiaries (the “**Group**”) is principally engaged in research, development and production of monoclonal antibody drugs for cancers and autoimmune diseases and transfer of intellectual property.

The immediate holding company of the Company is Asia Mabtech Limited, a limited liability company incorporated in the British Virgin Islands, which is ultimately controlled by Mr. Guo Jianjun.

2. BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2021 has been prepared in accordance with IAS 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual consolidated financial statements for the year ended 31 December 2020.

This interim condensed consolidated financial information is presented in Renminbi (“**RMB**”) and all values are rounded to the nearest thousand except when otherwise indicated.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2020, except for the adoption of the following revised International Financial Reporting Standards ("IFRSs") for the first time for the current period's financial information.

Amendments to IFRS 9, IAS 39 IFRS 7, IFRS 4 and IFRS 16	<i>Interest Rate Benchmark Reform – Phase 2</i>
Amendment to IFRS 16	<i>Covid-19-Related Rent Concessions</i>
Amendment to IFRS 16	<i>Covid-19-Related Rent Concessions beyond 30 June 2021</i>

The adoption of these revised standards has had no significant financial effect on the Group's interim condensed consolidated financial information.

4. SEGMENT INFORMATION

Segment information

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

Geographical information

The Group's revenue during the reporting period is derived from one external customer which is located in the PRC and the Group's non-current assets are substantially located in the PRC, accordingly, no geographical information in accordance with IFRS 8 Operating Segments is presented.

Information about a major customer

Revenue of approximately RMB81,246,000 (unaudited) (during the six months ended 30 June 2020: Nil (unaudited)) was derived from an intellectual property transfer agreement to a single customer.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

5. REVENUE

An analysis of revenue is as follows:

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
<i>Revenue from contracts with a customer</i>		
Revenue from intellectual property transfer agreement on CMAB806 – at a point in time	81,246	–

In January 2017, the Group entered into an agreement with an independent third-party customer to transfer an intellectual property in relation to CMAB806, at a consideration of RMB65,180,000 and further increased to RMB82,180,000 pursuant to two supplementary agreements signed in September 2019 and February 2020. The Group recognized revenue from this contract during the reporting period since the control of rights of the intellectual property had been transferred to the customer. The cost incurred to fulfil this contract, amounting to RMB16,769,000 (Unaudited) was charged to cost of sales during the six months ended 30 June 2021 and was included in contract costs as at 31 December 2020, respectively.

The following table shows the amounts of revenue recognized in the current reporting period that were included in the contract liabilities at the beginning of the reporting period:

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Revenue from intellectual property transfer agreement on CMAB806	70,058	–

Intellectual property transfer agreement with a customer

In December 2020, the Group entered into an agreement with an independent third-party customer to transfer an intellectual property in relation to CMAB809 at a consideration of RMB50,000,000. The Group did not recognize revenue from this contract during the reporting period since the control of rights of the intellectual property had not been transferred to the customer and no cost incurred to fulfil this contract as at 30 June 2021.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

5. REVENUE (continued)

Contract development and manufacturing agreement with a customer

In May 2021, the Group entered into an agreement with an independent third-party customer for contract development and manufacturing in relation to CMAB806, at a consideration of RMB43,860,000, while RMB16,144,000 has been received as at 30 June 2021. The Group did not recognize revenue from this contract during the reporting period since the control of rights of the deliverables had not been transferred to the customer. The cost incurred to fulfil this contract, amounting to RMB850,000 (unaudited) at 30 June 2021, was capitalized as cost to fulfil the contract and was included in contract costs in the interim condensed consolidated statement of financial position.

6. OTHER INCOME

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Bank interest income	1,043	8,173
Government grants and subsidies related to income	2,515	12,766
	3,558	20,939

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

7. OTHER GAINS AND LOSSES

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Net foreign exchange (losses)/gains	(4,646)	13,677
Others	(73)	5,389
	(4,719)	19,066

8. FINANCE COSTS

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Interest on bank loans	–	1,235
Interest on lease liabilities	1,267	1,389
	1,267	2,624

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

9. LOSS BEFORE TAX

Loss before tax for the period has been arrived at after charging/(crediting):

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Depreciation for plant and equipment	14,085	7,746
Depreciation for right-of-use assets	4,569	3,937
Loss on disposal of plant and equipment	73	–
Government grants and subsidies related to income	(2,515)	(12,766)
Staff cost (including directors' emoluments):		
– Independent non-executive directors' fee	151	163
– Salaries and other benefits	33,505	26,356
– Retirement benefit scheme contributions	3,065	1,120
– Share-based payment expenses	6,570	6,872
– Consultation fee	336	335
	43,627	34,846
Auditors' remuneration	700	600
Short-term lease payment	83	–
Expense incurred in intellectual property transfer agreement on CMAB807	66,038	–
Cost of intellectual property transfer agreement on CMAB806	16,769	–
Cost of inventories recognized as expense (included in research and development expense)	12,432	11,193

10. INCOME TAX EXPENSE

The Company was incorporated in the Cayman Islands and is exempted from income tax.

No Hong Kong profits tax was provided for as there was no estimated assessable profit of the Group's Hong Kong subsidiary that was subject to Hong Kong profits tax during the periods presented in the interim condensed consolidated financial information.

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 interim condensed consolidated financial information.

Deferred taxation had not been recognized on the unused tax losses and deductible temporary differences since it is not probable that the taxable profits will be available against which the tax losses and deductible temporary differences can be utilized in the foreseeable future.

11. DIVIDENDS

No dividend was paid or proposed for ordinary shareholders of the Company during the six months ended 30 June 2021, nor has any dividend been proposed since the end of the reporting period (during the six months ended 30 June 2020: Nil).

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY

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

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Loss attributable to ordinary equity holders of the Company for the purpose of calculating basic and diluted loss per share	(145,161)	(54,188)

	For the six months ended 30 June	
	2021 '000 (Unaudited)	2020 '000 (Unaudited)
Weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share	4,124,080	4,124,080

The calculation of diluted loss per share for the six months ended 30 June 2021 and 2020 did not assume the exercise of the pre-IPO share options since its inclusion would be anti-dilutive.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

13. PLANT AND EQUIPMENT

During the six months ended 30 June 2021, the Group acquired assets with a cost of RMB15,287,000 (unaudited) including RMB13,696,000 (unaudited) of construction in process (for the six months ended 30 June 2020: RMB170,201,000 (unaudited) including RMB165,279,000 (unaudited) of construction in process).

During the six months ended 30 June 2021, the grants related to construction of plant in Taizhou of RMB33,109,000 (unaudited) received in 2019 were deducted from the carrying amount of the assets upon the compliance of the Group with the conditions attached to the grants and the government acknowledged acceptance (for the six months ended 30 June 2020: Nil (unaudited)).

14. OTHER NON-CURRENT ASSETS

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Prepayment for acquisition of plant and equipment <i>(note a)</i>	70,207	44,070
Deposit for construction of production facilities	3,000	3,000
VAT recoverable <i>(note b)</i>	31,430	34,224
	104,637	81,294

Notes:

- a. Prepayment for acquisition of plant and equipment is mainly related to the new production facilities on the parcel of industrial land of approximately 100,746 square meters in Taizhou Hi-tech Zone.
- b. VAT recoverable is presented in prepayments and other receivables and other non-current assets based on the management's estimation of the amount of VAT recoverable to be utilized within one year.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

15. TRADE RECEIVABLES

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Trade receivables from a third party	11,468	–

The Group's trade receivables are generated from the intellectual property transfer agreement on CMAB806 and were received in July 2021.

The ageing of the trade receivables as at the end of each of the reporting period, based on the date of the service rendered, is less than three months and the expected credit loss is minimal.

The Group does not hold any collateral or other credit enhancements over its trade receivables. Trade receivables are non-interest-bearing.

16. PREPAYMENTS AND OTHER RECEIVABLES

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Other receivables	1,110	1,224
Prepayments for research and development services	13,813	11,177
Other deposits and prepayments	8,943	4,185
VAT recoverable (<i>note</i>)	14,525	15,087
	38,391	31,673

Note: VAT recoverable is presented in prepayments and other receivables and other non-current assets based on the management's estimation of the amount of VAT recoverable to be utilized within one year.

17. PLEDGED BANK DEPOSITS/CASH AND BANK BALANCES

Pledged bank deposits

The current pledged bank deposits at 30 June 2021 and 31 December 2020 were pledged to a bank as collateral for the issue of a payment guarantee for a construction contract, which were interest-bearing at a fixed rate of 0.3% per annum. The pledge will be expired in September 2021.

Cash and bank balances

Cash and bank balances comprise of cash at banks and short-term bank deposits with an original maturity of three months or less. Cash and bank balances earns interest at floating rates based on daily bank deposit rates. Short-term time deposits are made for varying periods of between one day and three months depending on the immediate cash requirements of the Group and earn interest at the respective short-term time deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default. The carrying amounts of the cash and bank balances approximate to their fair values.

18. TRADE AND OTHER PAYABLES

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Trade payables	6,472	4,466
Accrued expenses for research and development services	43,558	25,334
Other payables for purchases of plant and equipment	34,282	54,088
Salary and bonus payables	8,361	11,185
Other taxes payable	437	594
Accrued listing expenses and issue costs	10,545	10,646
Other payables	2,330	6,984
	105,985	113,297

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

18. TRADE AND OTHER PAYABLES (continued)

Payment terms with suppliers are mainly on credit with 60 days from the time when the goods and/or services are received from the suppliers. The aging analysis of the trade payables presented based on the receipt of goods/services by the Group at the end of the reporting period is as follows:

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Within 60 days	4,691	2,997
Over 60 days but within 1 year	1,538	1,469
Over 1 year	243	–
	6,472	4,466

19. SHARE-BASED PAYMENT TRANSACTIONS

Equity-settled share option scheme of the Company

The Company's Pre-IPO Share Option Scheme (the "Scheme") were adopted pursuant to a resolution passed on 10 August 2018 for the primary purpose of providing incentives to directors of the Company and eligible employees of the Group. Under the Scheme, 1,875,000 options were granted on 18 August 2018 to directors of the Company and eligible employees of the Group to subscribe for shares in the Company, which will expire on 17 August 2028.

The Scheme has a service condition that shall vest over an 8-year period, with 20%, 20%, 20%, 20% and 20% of the total number of the options granted to be vested on the fourth, fifth, sixth, seventh and eighth anniversary of the listing date, respectively.

The exercise price in relation to each option granted shall be the final offer price per share at which the shares are to be acquired by the investors pursuant to the Hong Kong Public Offering and the International Offering, which shall not be less than the par value of the shares, provided that the exercise price shall be adjusted in the event of any capitalization issue, rights issue, open offer, sub-division, consolidation of shares, or reduction of capital of the Company.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

19. SHARE-BASED PAYMENT TRANSACTIONS (continued)

Equity-settled share option scheme of the Company (continued)

On 8 April 2019, a shareholders' resolution about capitalization issue was passed and after taking into account of the capitalization issue the number of share options were increased to 83,512,500.

Particulars and movements in the Scheme are as follows:

Date of grant	Outstanding at 1 January 2021	Granted	Exercised	Forfeited	Outstanding at 30 June 2021 (Unaudited)
18 August 2018	80,046,901	–	–	100,256	79,946,645

The Group recognized the total expense of RMB6,570,000 (unaudited) for the six months ended 30 June 2021 in relation to share options granted by the Company (for the six months ended 30 June 2020: RMB6,872,000 (unaudited)).

The fair value of the options granted was determined using the Binomial pricing model at the grant date.

20. CAPITAL COMMITMENTS

The Group had capital commitments for equipment purchase and building construction under contracts as follows:

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Contracted but not provided (<i>note</i>)	172,571	138,014

Note: The capital commitments are mainly related to the new production facilities on the parcel of industrial land of approximately 100,746 square meters in Taizhou Hi-tech Zone.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

21. RELATED PARTY TRANSACTIONS

(a) The Group had the following transactions with related parties during the period:

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Expense incurred in intellectual property transfer agreement: Shanghai Biomabs Pharmaceuticals Co., Ltd. ("Biomabs") (note a)	66,038	–
Expenses incurred in clinical business paid by a related party on behalf of the Group: Biomabs	3,124	1,561
Repayments to a related party regarding to the expenses incurred in clinical business paid by a related party on behalf of the Group: Biomabs	383	3,129
Interest on lease liabilities to a related party: Biomabs	108	251

Note:

- a. Biomabs is ultimately controlled by a close family member of the controlling shareholder. In March 2021, the Group entered into an agreement with Biomabs in relation to acquire the intellectual property in connection with CMAB807 from Biomabs at a consideration of RMB66,038,000 (excluding value added tax). Till 30 June 2021, the outstanding payable balance was accrued to RMB47,170,000 (unaudited). For further details regarding the acquisition of CMAB807, please refer to the announcement of the Company dated 1 March 2021, and the circular dated 13 April 2021 published on the websites of the Stock Exchange and the Company.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

21. RELATED PARTY TRANSACTIONS (continued)

(b) Outstanding balances with related parties:

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Rental deposit to a related party: Biomabs	411	411
Amount due to a related party: Trade payables Biomabs	47,277	54
Non-trade payables Biomabs	2,762	21
	50,039	75
Lease liabilities payable to Biomabs: Within one year	2,985	4,386

Non-trade payables to Biomabs are unsecured, non-interest-bearing and repayable on demand.

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

21. RELATED PARTY TRANSACTIONS (continued)

(b) Outstanding balances with related parties: (continued)

Payment terms with suppliers are mainly on credit with 60 days from the time when the goods and/or services are received from the suppliers. The ageing analysis of the trade payables presented based on the receipt of goods/services by the Group at the end of the reporting period is as follows:

	30 June 2021 RMB'000 (Unaudited)	31 December 2020 RMB'000 (Audited)
Within 60 days	47,277	39
Over 60 days but within 1 year	–	15
	47,277	54

The lease liabilities payable to Biomabs represent capitalization of a forty-month secured building lease entered with Biomabs, which commenced from 1 September 2018. For the six months ended 30 June 2021, the Group paid Biomabs in an amount of RMB1,509,000 (unaudited) in connection with this lease arrangement (for the six months ended 30 June 2020: RMB2,640,000 (unaudited)).

Notes to Interim Condensed Consolidated Financial Information

30 June 2021

21. RELATED PARTY TRANSACTIONS (continued)

(c) Compensation of key management personnel of the Group

	For the six months ended 30 June	
	2021 RMB'000 (Unaudited)	2020 RMB'000 (Unaudited)
Salaries and other benefits	2,538	2,558
Retirement benefit scheme contributions	134	24
Directors' fee	151	163
Share-based compensation	2,948	5,621
Consultation fee	336	335
	6,107	8,701

22. EVENT AFTER THE REPORTING PERIOD

On 12 July 2021, the new drug application of CMAB008, a core product of the Company, was approved by the National Medical Products Administration of the PRC.

Definitions

In this interim report, the following expressions have the meanings set out below unless the context requires otherwise.

“Asia Mabtech”	Asia Mabtech Limited, a limited liability company incorporated in the BVI on November 23, 2017 and one of the Controlling Shareholders
“Asia Pacific Immunotech Venture”	Asia Pacific Immunotech Venture Limited, a limited liability company incorporated in the BVI on July 23, 2018 and one of the Controlling Shareholders
“Audit Committee”	the audit committee of the Board
“Biomabs”	Shanghai Biomabs Pharmaceuticals Co., Ltd. (上海百邁博製藥有限公司), a limited liability company incorporated in the PRC on October 16, 2009 and a direct wholly-owned subsidiary of Sinomab as of the date of this interim report
“Board” or “Board of Directors”	the board of Directors of the Company
“CDH”	CDH PE and CDH VC
“CDH PE”	CDH Mabtech Limited, a limited liability company incorporated in the Cayman Islands
“CDH VC”	Genemab Holding Limited, a limited liability company incorporated in the BVI
“CG Code”	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
“Company”	Mabpharm Limited (迈博药业有限公司), an exempted company incorporated in the Cayman Islands with limited liability on June 1, 2018 and whose Shares are listed on the Stock Exchange
“connected person(s)”	has the meaning ascribed to it under the Listing Rules

Definitions

“Controlling Shareholders”	has the meaning ascribed thereto in the Listing Rules and, unless the context otherwise requires, refers to Mr. Guo Jianjun, Guo Family Trustee, Asia Pacific Immunotech Venture, Asia Mabtech and United Circuit
“Core Product(s)”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for the purpose of this interim report, our Core Products include CMAB007, CMAB009 and CMAB008
“Director(s)”	the director(s) of our Company
“FH Investment”	Fortune-Healthy Investment Limited, a limited liability company incorporated in the BVI
“Global Offering”	has the meaning ascribed to it under the Prospectus
“Group”, “our Group”, “the Group”, “we”, “us”, or “our”	the Company and its subsidiaries from time to time
“Guo Family Trust”	Guo Family Trust, a trust created by Mr. Guo Jianjun on August 8, 2018 under the laws of BVI for the benefit of his family members, for which Guo Family Trustee serves as trustee
“Guo Family Trustee”	Guo Family (PTC) Limited, a limited liability company incorporated in the BVI on March 1, 2018 and the trustee of the Guo Family Trust
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars” or “HK dollar” or “HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited
“independent third party(ies)”	any entity or person who is not a connected person of the Company within the meaning ascribed thereto under the Listing Rules
“IPO”	initial public offering

Definitions

“Listing”	the listing of our Shares on the Main Board of the Stock Exchange on May 31, 2019
“Listing Date”	May 31, 2019, being the date on which the Shares were listed on the Main Board of the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange
“Main Board”	the Main Board of the Stock Exchange
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers contained in Appendix 10 to the Listing Rules
“NMPA”	National Medical Products Administration (國家藥品監督管理局) of China, formerly known as China’s Food and Drug Administration (“CFDA”) (國家食品藥品監督管理局) or China’s Drug Administration (“CDA”) (國家藥品監督管理局); references to NMPA include CFDA and CDA
“PRC”	the People’s Republic of China, excluding, for the purposes of this interim report, Hong Kong, the Macau Special Administrative Region and Taiwan
“Prospectus”	the prospectus issued by the Company on May 20, 2019 in connection with the Hong Kong public offering of the Shares
“Reporting Period”	the six months from January 1, 2021 to June 30, 2021
“RMB”	Renminbi, the lawful currency of the PRC
“Shares”	ordinary share(s) in the capital of the Company with nominal value of US\$0.0001 each
“Shareholder(s)”	holder(s) of Share(s)
“Sinomab”	Sinomab Limited (formerly known as Mabtech Limited), a limited liability company incorporated in the Cayman Islands on September 4, 2014, and a company which a controlling shareholder of the Company and his associate indirectly control 66.67% voting rights in aggregate as of the date of this interim report

Definitions

“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Taizhou Biotech”	Taizhou Mabtech Biotechnology Limited* (泰州邁博太科生物技術有限公司), a limited liability company incorporated in the PRC on November 24, 2016 and an indirect wholly-owned subsidiary of the Company
“Taizhou Pharmaceutical”	Taizhou Mabtech Pharmaceutical Limited* (泰州邁博太科藥業有限公司), a limited liability company incorporated in the PRC on February 4, 2015 and an indirect wholly-owned subsidiary of the Company
“United Circuit”	United Circuit Limited (域聯有限公司), a limited liability company incorporated in the BVI on August 25, 2015 and one of the Controlling Shareholders

* *For Identification Only*

Glossary of Technical Terms

“adalimumab”	a first-line recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF) (which binds specifically to TNF-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors) used for rheumatoid arthritis
“allergic asthma”	a common long-term inflammatory disease of the airways of the lungs. It is characterized by variable and recurring symptoms, reversible airflow obstruction, and bronchospasm. Symptoms include episodes of wheezing, coughing, chest tightness, and shortness of breath. These episodes may occur a few times a day or a few times per week. Depending on the person, they may become worse at night or with exercise
“autoimmune disease”	diseases such as rheumatoid arthritis and lupus which arise from an abnormal immune response of the body against substances and tissues normally present in the body
“biosimilar”	also known as follow-on biologic or subsequent entry biologic. It is a biologic medical product that is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original “innovator” products and can be manufactured when the original product’s patent expires. A biosimilar product is similar in terms of quality, safety and efficacy to a reference medicinal product, which has been granted a marketing authorisation on the basis of a complete dossier in the community
“bronchiospasm”	a sudden constriction of the muscles in the walls of the bronchioles due to the release (degranulation) of substances from mast cells or basophils under the influence of anaphylatoxins, which causes breathing difficulties

Glossary of Technical Terms

"canakinumab"	a recombinant, fully human anti-IL-1 β monoclonal antibody that belongs to the IgG1 κ isotype subclass used for periodic fever syndrome and systemic juvenile idiopathic arthritis, which binds to human IL1 β and neutralizes its activity by blocking its interaction with the IL-1 receptors, but does not bind IL-1 α or IL-1ra
"carcinoma"	a type of cancer that develops from epithelial cells. Specifically, a carcinoma is a cancer that begins in a tissue that lines the inner or outer surfaces of the body, and that arises from cells originating in the endodermal, mesodermal or ectodermal germ layer during embryogenesis
"cell culture"	the process by which cells are grown under controlled conditions, generally outside of their natural environment
"cell line"	a cell culture developed from a single cell and therefore consisting of cells with a uniform genetic makeup
"cetuximab"	an EGFR antagonist approved by the FDA for the treatment of KRAS wild-type, EGFR-expressing, metastatic colorectal cancer under certain conditions
"cGMP"	current Good Manufacturing Practice
"chemotherapy"	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
"Chinese hamster ovary cell" or "CHO"	the ovary of the Chinese hamster, of which cell lines are derived from and often used in biological and medical research and commercial production of therapeutic proteins
"CMAB007"	one of our Core Products, a recombinant humanized anti-IgE monoclonal antibody and our new drug candidate based on omalizumab
"CMAB008"	one of our Core Products, a recombinant anti-TNF-alpha chimeric monoclonal antibody and our new drug candidate based on infliximab

Glossary of Technical Terms

"CMAB009"	one of our Core Products, a recombinant anti-EGFR chimeric monoclonal antibody and our new drug candidate based on cetuximab
"CMAB810"	a pre-clinical stage biosimilar drug candidate based on Perjeta, a recombinant humanized monoclonal antibody for the treatment of breast cancer
"CMAB816"	a pre-clinical stage biosimilar drug candidate based on Ilaris for the treatment of periodic fever syndrome and systemic juvenile idiopathic arthritis
"CMAB819"	a phase I clinical trial new drug candidate based on nivolumab for the treatment of metastatic non-small cell lung cancer and hepatocellular carcinoma
"CRC"	clinical research coordinator
"CRO"	a contract research organization, which provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research and development services outsourced on a contract basis
"cytokine"	a broad and loose category of small proteins that are important in cell signaling. Their release has an effect on the behavior of target cells
"DNA"	deoxyribonucleic acid
"EGFR"	epidermal growth factor receptor
"head-to-head clinical trials"	clinical trials conducted to prove the similarities between drug candidates and the reference drugs, in order to support the safety and efficacy of such drugs
"HER2"	human epidermal growth factor receptor 2
"ICS"	inhaled corticosteroids

Glossary of Technical Terms

"ICS/LABA"	inhaled corticosteroid/long acting beta adrenoceptor agonists treatment
"IgE"	immunoglobulin E
"IgG1 κ " or "IgG1 kappa"	immunoglobulin G (IgG), a type of antibody. Representing approximately 75% of serum antibodies in humans, IgG is the most common type of antibody found in blood circulation. IgG molecules are created and released by plasma B cells. Each IgG has two antigen binding sites. There are four IgG subclasses (IgG1, 2, 3, and 4) in humans, named in order of their abundance in serum (IgG1 being the most abundant). IgG antibodies are large molecules of about 150 kDa made of four peptide chains. It contains two identical clasheavy chains of about 50 kDa and two identical light chains of about 25 kDa, thus a tetrameric quaternary structure. There are two types of light chain in humans kappa (κ) chain and lambda (λ) chain. Only one type of light chain is present in a typical antibody, thus the two light chains of an individual antibody are identical. IgG1 κ is an antibody molecule which contains two γ 1 heavy chains and two κ light chains
"IL-1ra"	IL-1 receptor antagonist
"IL-1 β "	interleukin-1 β
"immunoglobulin" or "Ig"	an antibody (Ab), also known as an immunoglobulin (Ig). It is a large, Y-shaped protein produced mainly by plasma cells that is used by the immune system to neutralize pathogens such as pathogenic bacteria and viruses. The antibody recognizes a unique molecule of the pathogen, called an antigen, via the Fab's variable region
"infliximab"	a chimeric IgG1 κ monoclonal antibody (composed of human constant and murine variable regions) specific for human tumor necrosis factor-alpha used for adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate

Glossary of Technical Terms

"in vitro"	Latin for "in glass", studies in vitro are conducted using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
"in vivo"	Latin for "within the living", studies in vivo are those in which the effects of various biological or chemical substances are tested on whole, living organisms as opposed to a partial or dead organism, or those done in vitro
"LABA"	long-acting beta2-agonists
"mCRC"	metastatic colorectal cancer
"monoclonal antibody" or "mAb"	an antibody produced by a single clone of immune cells or cell line and consisting of identical antibody molecules
"nivolumab"	a human immunoglobulin G4 (IgG4) monoclonal antibody, which targets the negative immunoregulatory human cell surface receptor programmed death-1 (PD1, PCD1,) with immune checkpoint inhibitory and antineoplastic activities
"omalizumab"	anti-IgE humanized IgG1 κ monoclonal antibody used to reduce sensitivity to allergens
"oncology"	a branch of medicine that deals with tumors, including study of their development, diagnosis, treatment and prevention
"pathogen"	infectious agent such as a bacterium, fungus, virus, or other micro-organism
"PD"	programmed death
"pertuzumab"	a recombinant humanized monoclonal antibody, which targets the extracellular (domain II) of the human epidermal growth factor receptor 2 protein (HER2) and, thereby, blocks heterodimerization of HER2 with other HER family members, including HER1, HER3 and HER4

Glossary of Technical Terms

“pharmacodynamics”	the study of how a drug affects an organism, which, together with pharmacokinetic, influences dosing, benefit, and adverse effects of the drug
“pharmacokinetic”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“phase I clinical trial(s)”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“phase II clinical trial(s)”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“phase III clinical trial(s)”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“pre-clinical stage”	testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“R&D”	research and development
“RA” or “rheumatoid arthritis”	a chronic, systemic inflammatory disorder that may affect many tissues and organs, but principally attacks synovial joints
“recombinant”	the formation by the processes of crossing-over and independent assortment of new combination of genes in progeny that did not occur in the parents
“RSV”	respiratory syncytial virus

Glossary of Technical Terms

“TNF”	tumor necrosis factor
“TNF- α ” or “TNF-alpha”	tumor necrosis factor (TNF, tumor necrosis factor alpha, TNF α , cachexin, or cachectin). It is a cell signaling protein (cytokine) involved in systemic inflammation and is one of the cytokines that make up the acute phase reaction. It is produced chiefly by activated macrophages, although it can be produced by many other cell types such as CD4+ lymphocytes, NK cells, neutrophils, mast cells, eosinophils, and neurons
“vector”	an agent (such as a plasmid or virus) that contains or carries modified genetic material (such as recombinant DNA) and can be used to introduce exogenous genes into the genome of an organism